SECRETARÍA EJECUTIVA
COMISCA
CONSEJO DE MINISTROS DE SALUD DE CENTROAMÉRICA Y REPÚBLICA DOMINICANA

SICA
Sistema de la Integración Centroamericana

USER MANUAL

CITIZEN NOTIFICATION

Noti-FACEDRA

Portal Regional de notificación en línea de sospecha de reacciones adversas a medicamentos y vacunas de uso humano.

Content

Introduction

The Noti-FACEDRA portal is part of the FACEDRA Regional System (Central American Pharmacovigilance Data of Adverse Reactions to Medicines and Vaccines for Human Use), which is managed by the Executive Secretariat of the Council of Ministers of Health of Central America and the Dominican Republic (SE-COMISCA) in coordination with the National Centres/ Units/ Programmes competent in the pharmacovigilance field in the Medicines Regulatory Authorities of the Member States of the Central American Integration System (SICA) region, as part of the capacity building and consolidation of the Central American Regional Pharmacovigilance Program and of the national pharmacovigilance actions for Belize, Guatemala, El Salvador, Honduras, Nicaragua, Costa Rica, Panama and the Dominican Republic.

Noti-FACEDRA is an Information tool that allows the online notification process of suspected adverse reactions to medicines and vaccines (for human use) to the National Pharmacovigilance Centers in Central America and the Dominican Republic. Therefore, it is important for patients to inform their doctor, pharmacist or other health professional about possible adverse reactions derived from the use of medications and vaccines; taking into account that citizens can do so directly through the regional portal **Noti-FACEDRA 2.1.**

This electronic notification tool contributes to knowing in a prompt and timely manner, the adverse reactions of medicines and vaccines used in both the private sector and in national health systems.

With **Noti-FACEDRA 2.1**, national capacities will be strengthened for the surveillance of the safety and effectiveness of medicines and vaccines authorized by the drug regulatory authorities of the SICA region.

General considerations

All medications can occasionally cause unwanted effects, also known as adverse drug and vaccine reactions (ADRs). Sometimes, ADRs can appear after a person has stopped using the medication, or, even after a vaccine has been administered, while some ADRs may not be discovered until many people have used the medication over a long period of time.

If you are concerned about a symptom that you think may be an adverse reaction, please consider the following:

1. Review the medication package insert. It lists known adverse reactions and advises you on what to do.

2. Talk to your doctor or pharmacist and inform them of your concerns or fears, as well as any possible adverse reactions you may have experienced. If you believe you have experienced an adverse reaction to a medication or vaccine, you can also report it using the electronic form available at www.notificacentroamerica.net.

The electronic form is intended to be a simpler and faster way to notify your National Regulatory Authority of a potential adverse reaction that occurs with the use of a medicine or following the administration of a vaccine.

WHAT SHOULD YOU NOTIFY?

You may report suspected adverse reactions to any medicine or vaccine for human use, including prescription, non-prescription, or herbal medicines. Do not hesitate to do so if you suspect any problems with the use of these products.

It is especially useful to receive information about suspected adverse reactions that occur in patients in the following cases:

- When not mentioned in the accompanying leaflet of the medicine or vaccine.
- It has caused you problems that you believe interfere with your normal activities.
- It is associated with the use of a drug or vaccine recently introduced to the national market.
- It occurs when you are taking more than one medication, and can be caused by an interaction between them, or with some foods.

WHO CAN NOTIFY?

Anyone can report, whether you experience an adverse reaction that may be due to the medication administered, or, you can report adverse reactions that your children, an older adult under your care, or a close person may experience.

HOW TO COMPLETE THE FORM?

To fill out the form you will need to provide information on four important aspects:

1) Details of the possible adverse reaction that may occur after the administration of a medication or vaccine.

2) Provide the brand name / generic name of the medication that you suspect caused the adverse reaction.

3) Details of the general data of the person experiencing the adverse reaction.

4) Information about the person making the notification will also be required.

The electronic form in **Noti-FACEDRA** (accessible from www.notificacentroamerica.net) has "help" elements that appear as a question mark (?**)**.

If you need this help, hover your cursor over these symbols and a drop-down menu with help text will appear. Keep in mind that the form fields are dynamic and will provide suggestions as you enter information.

ON THE PROTECTION OF DATA INCLUDED IN Noti-FACEDRA

All information provided will be protected and will not be disclosed to third parties, in order to comply with national information confidentiality provisions.

How is information provided by reporting suspected adverse reactions used to improve drug safety?

The National Pharmacovigilance Centers of Central America and the Dominican Republic evaluate this data, along with information collected from clinical studies and other sources on the use of medications. When there is sufficient information to determine that a group of similar cases of suspected adverse reactions are likely caused by a medication or vaccine, this information will be included in the medication's safety information and in the package insert.

On other occasions, this information is used for communication purposes to reduce the risks associated with the use of certain medications or vaccines prescribed by certain specialists, or to recommend their use as a second choice. The Drug Regulatory Authorities of Central America and the Dominican Republic also use this information to issue Information Alerts, which are available on institutional websites, or to prepare and distribute newsletters.

How to access the platform?

The Regional Online Reporting Portal for Suspected Adverse Reactions to Medicinal Products for Human Use, known as **Noti-FACEDRA,** is available at www.notificacentroamerica.net.

The online reporting portal aims to facilitate the reporting of suspected adverse reactions to medications or vaccines detected by healthcare professionals, citizens, and the pharmaceutical industry, so that they can be promptly reported to the National Pharmacovigilance Centers in their country of residence, so that the respective analysis can be conducted.

Noti-FACEDRA portal, you must follow these steps:

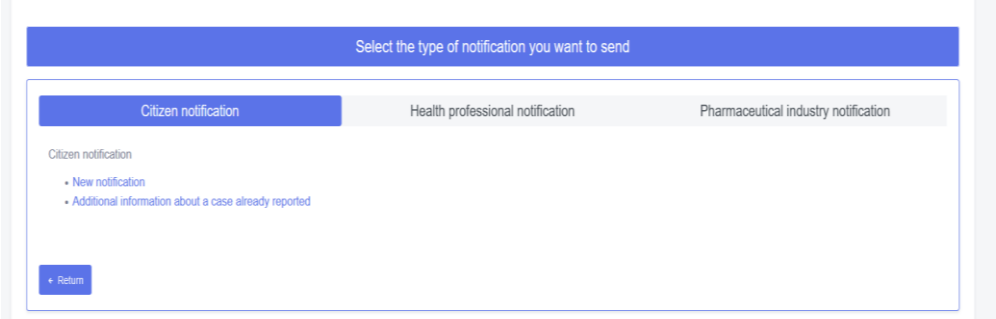
1. Type the following into the address bar of your preferred browser: www.notificacentroamerica.net where the welcome screen shown below will be displayed:

2

You will then need to click on the map to select your country of residence.

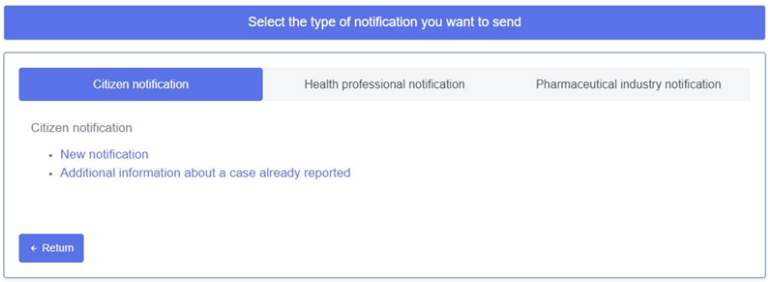
3

Then the **Main Menu** will be displayed, which consists of three options for the type of notification to be sent. Select the "**Citizen Notification**" form to start the online report of suspected adverse reactions to medicines or vaccines through Noti-FACEDRA,

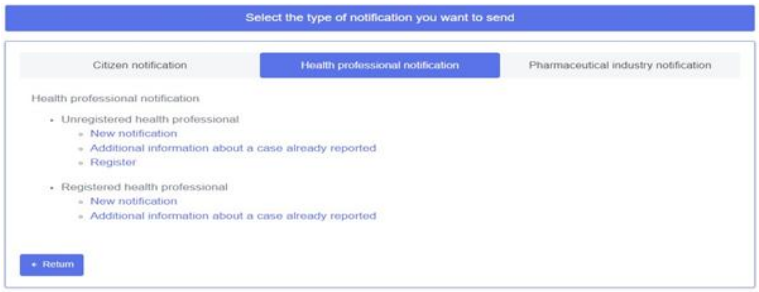


Main Menu

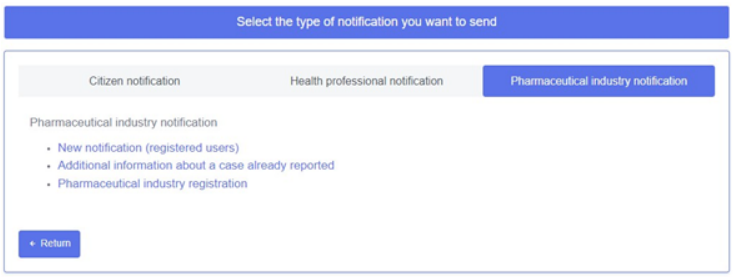
1. The option to access the form called **Citizen Notification** allows access to all people who wish to directly report suspected adverse reactions to medications or vaccines that are detected by them. This includes patients or their caregivers, in case the patient cannot do so directly.



2. The second option provides access to the **Health Professional Notification form,** which enables the reporting of suspected adverse reactions that may be detected by health professionals during their routine practice.



3. The third option provides access to the **Pharmaceutical Industry Notification form** , so that industries registered on the platform can report adverse reactions to their medications.



Citizen notification process

In order for citizens to be able to report using the **Noti-FACEDRA electronic form,** they must have the necessary information for the process of reporting suspected adverse reactions to a medication, including prescription, non-prescription, or herbal medications. Do not hesitate to do so if you suspect any problem with the use of these products.

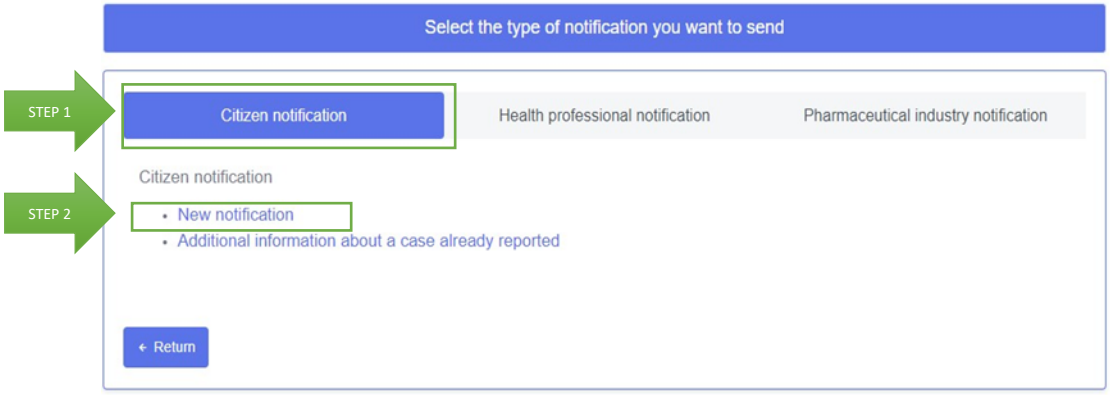
To fill out the form you will need to provide information on four important aspects:

1. ***Details of the possible adverse reaction detected.***
2. ***Provide the brand name or active ingredient of the medication that you suspect caused the adverse reaction.***
3. ***The data of the person who had the adverse reaction.***
4. ***Information about the person making the notification will also be required.***

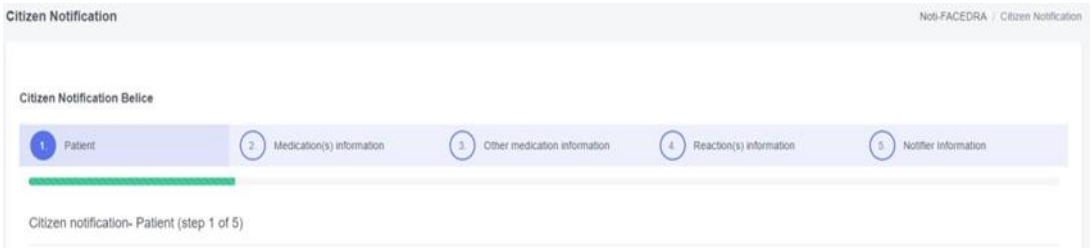
With this information available, citizens have everything they need to complete the electronic form through **Noti-FACEDRA.**

The process of a ***New Notification*** by Citizen begins by following these steps:

1. Select the **Citizen Notification option from the main menu.**
2. **Select New Notification** option to access the electronic case report form.

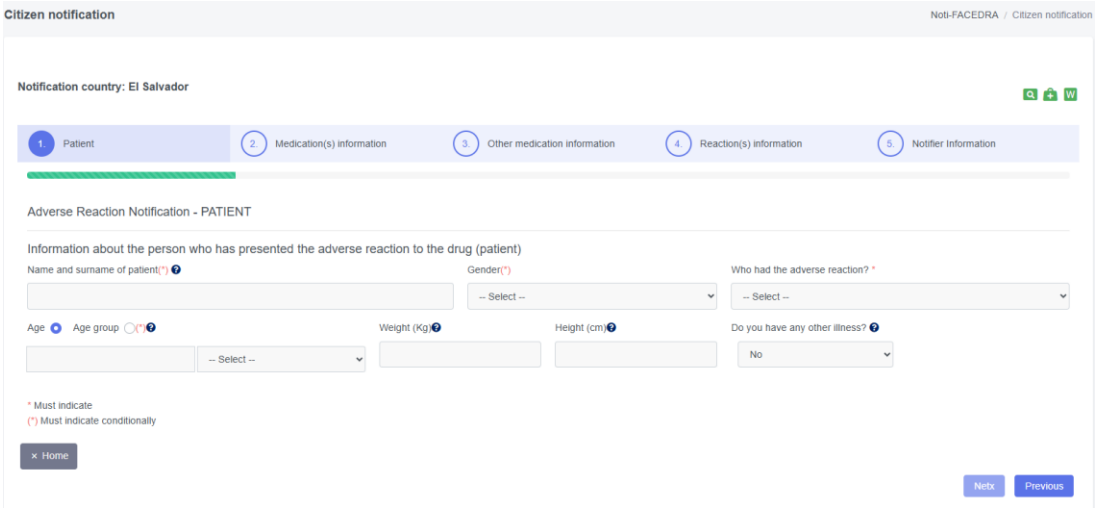


3. The fields of the notification form are presented; you must complete the information in the ***5 sections*** shown in the following figure:



Patient Data

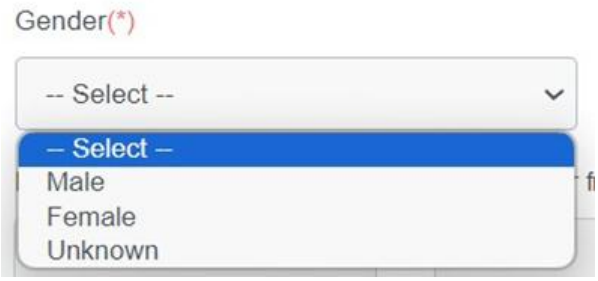
Step 1 of 5: Include in this section the information related to the person (patient) who has had the adverse reaction to the medication or vaccine:



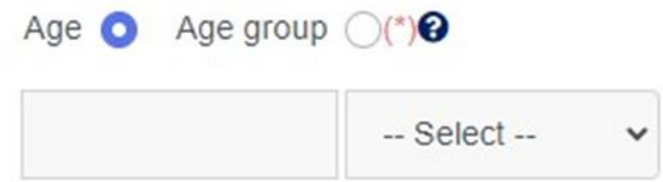
The following information must be completed:

a. **Patient's Name and Surname,** the patient's full name or initials must be entered. This information must be provided as mandatory information (*).

b. **"Gender",** one of the options shown in the figure must be selected, for example, Male or Female; this corresponds to information marked (*) which corresponds to mandatory information.



c. **For the report of the patient's Age,** there are two possibilities. The first option for Age, allows you to enter a numerical value, accompanied by the time unit, for example, decades, years, days, hours, months or weeks, as shown in the following figure:



The second option is by Age Group, in which the patient's age is expressed by age groups, selecting one of the options shown, for example: Newborn, Infant, Child, Adolescent, Adult or Elderly, as shown in the following figure:

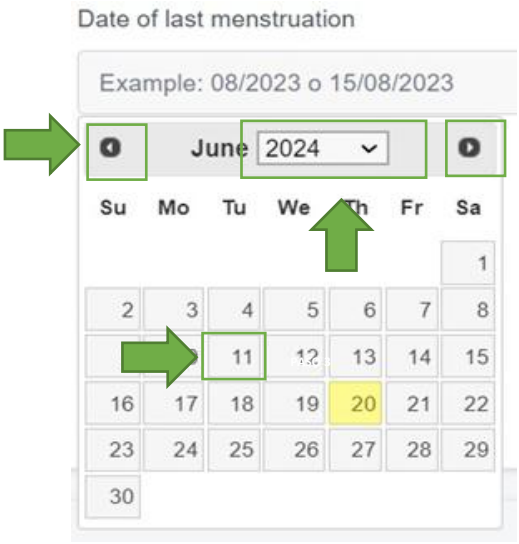
Information marked (*) corresponds to mandatory information and cannot be left blank.

d. **For reporting of the patient's Weight, the** weight data expressed in kilograms (kg) must be indicated, placing only the numerical value of the weight.

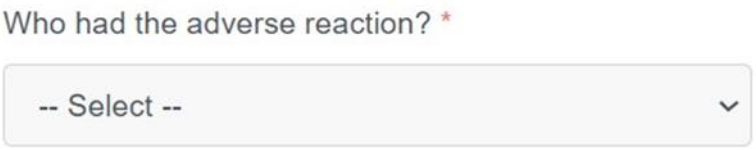
e. **For patient Height,** the value must be indicated in centimeters (cm), placing only the numerical value of the height.

f. **"Date of last menstruation",** this field will be displayed only if the patient is female. You must enter the date in month/year or day/month/year format. For example: 08/2023 or 01/01/2024. This information is not mandatory, so if you don't know or remember it, you can leave it blank.

You can use the drop-down calendar to make entering dates easier. To move between the different months of the year, just click the arrows in the top corners. To change the year, simply click on the current year text, which should display a list of available years. Simply select the corresponding year, then click on the day of the date you want to enter, and the date will automatically appear in the field in day/month/year format.



g. For the question **"Who had the adverse reaction?":** In this field it is necessary to select one of the three options shown in the figure.

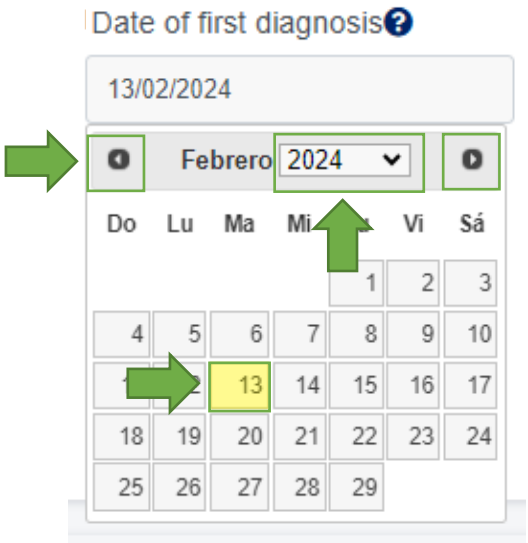


This field is marked (*) which corresponds to mandatory information and cannot be left blank.

h. For the question **"Do you have any other illness?",** it refers to the presence or absence of any illness (disease or condition) at the time the adverse reaction being reported occurs.
If you have a medical condition, you must select " ***YES*** " to display a new menu that will allow you to report the name of the condition you have and the date your doctor diagnosed it, as shown in the following figure:

In the **"Name of illness"** field, you must enter the name of the disease you suffer from. By typing the name, a menu of medical terminology will automatically appear to assist you. You can select one of these terms to report the disease you suffer from.

In the "**Date of First Diagnosis"** field, you must indicate the date you were diagnosed with the illness (disease or condition) you suffer from. To report the date, you can do so in month/year format, or if you remember the exact date of diagnosis, you can report it to us in day/month/year format. If you don't know this information, you can leave the field blank.



You can use the drop-down calendar to make entering dates easier. To move between the different months of the year, just click the arrows in the top corners. To change the year, simply click on the current year text, which should display a list of available years. Simply select the corresponding year, then click on the day of the date you want to enter, and the date will automatically appear in the field in day/month/year format.

Next, you will need to click on the "**Accept and Save illness**" button to save the information.

If you have more than one illness and wish to report them, you must fill out the aforementioned fields for each of the illnesses you suffer from, as long as each one is accepted and saved.

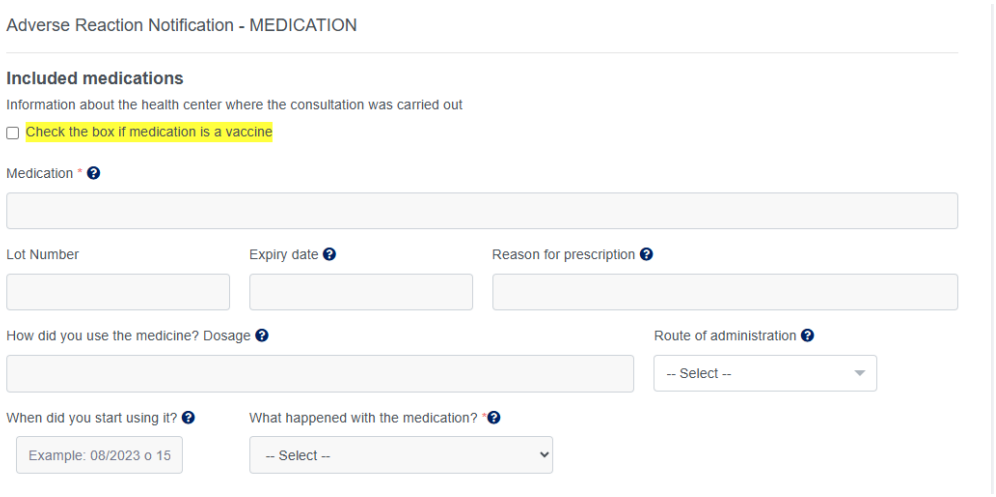
Step 1 ends by completing the information and clicking the "**Next"** button.

Medication Information

Step 2 of 5, called "**Medications Information(s**)", related to the necessary information about the medication or vaccine, which is suspected to be responsible for the adverse reaction, the patient must complete the following information:

Add Medication

a) **"Medication",** to facilitate information about the medication that may have caused the adverse reaction, in the field called "medication", you must enter the trade name of the medication or its active ingredient. As you type in this space, you can select the name of the suspected medication from the drop-down list, as shown in the following figure:



If you do not know or do not have the name of the medication available or do not remember it, you may enter the name of the active ingredient in the medication.

Please note that this is a field marked (*) that corresponds to mandatory information and cannot be left blank.

Before adding a drug's brand name, you should consider viewing or verifying the following information:

Brand Name: *This is the name under which the medication is sold in the market.*

Pharmaceutical Form: *This refers to the presentation in which the medication is administered. For example: Tablets or pills, Capsules, Injectable solution, Syrup, Cream or ointment, Suppositories.*

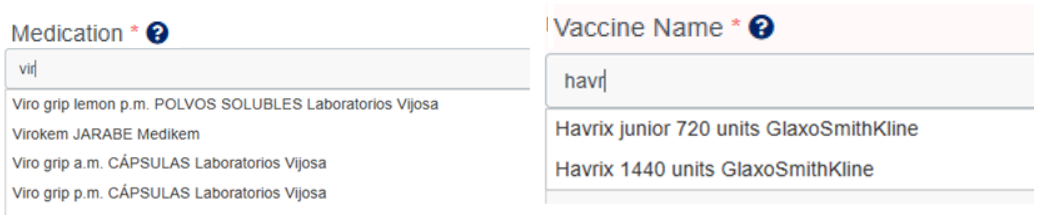
Marketing Authorization Holder: *This is the company or pharmaceutical laboratory authorized to sell the medication. It can be the manufacturer or a company that distributes it under its name.*

Concentration: *Indicates the amount of active ingredient in the medication's presentation. It is expressed in different units depending on the type of medication, such as mg (milligrams), mg/ml (milligrams per milliliter), and % (percentages) in creams and gels.*

If you have any questions about any of the information, you can ask your trusted pharmacist at a pharmacy near your home or at a health center after consulting your doctor.

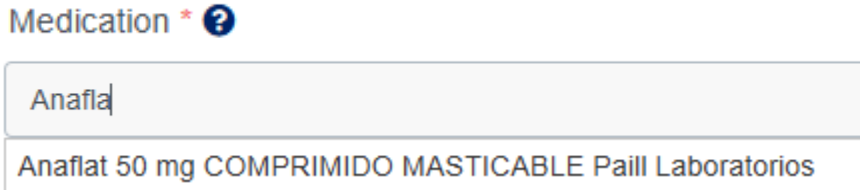
Recommendations on **how to correctly search for a drug's brand name in Noti-FACEDRA 2.1:**

I. In the Medication or Vaccine field, you must enter the **brand name you** want to report. The options that begin with the text entered in the field will then appear. For this example, scroll and a list of terms will be displayed.



Only brand names that match your entry and are available for sale in the country for which you are reporting the notification will be displayed. The drug options are structured in the following order:

Trade (Commercial) name + Concentration + Pharmaceutical form + Manufacturer name



If the medication has more than one strength, dosage form, or brand name, all available options will be displayed for more accurate reporting.

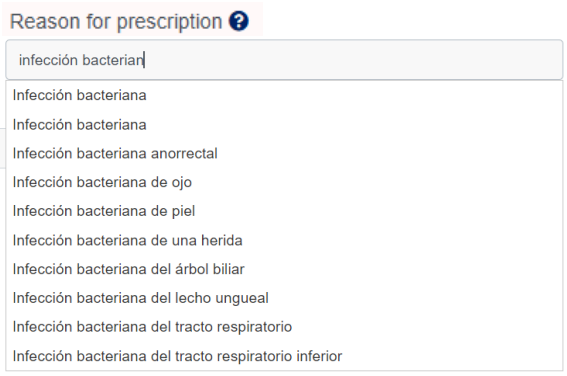
II. After having selected one of the self-complementing options, you must fill in the other fields (see the section “Add medication”, paragraphs b to j “Report of a suspected ADR due to vaccines”, paragraphs c to j as appropriate).

III. If the medication you want to report isn't listed in the auto-complete options, you can still report it by entering the name you know, adding the other information, and clicking "Accept and Save Medication" or "Accept and Save Vaccine."

Note: If the medication you want to report is not among the options shown, enter the name as you remember it. The platform will accept the text you enter in the medication name field.

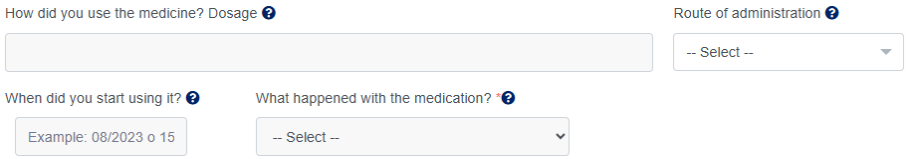
To report the **lot number and expiration date** of the suspected medication, you can find the information on the medication packaging. If it's not available or you don't know it, you can continue with the information entry process.

b) To answer the question **"Reason for prescription”** the patient must enter the use for which the medication was prescribed by their doctor. As the indication is entered

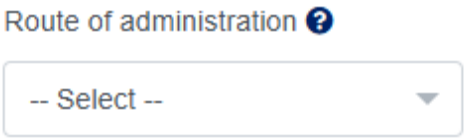


in this space, you can select one of the options from the drop-down list, as shown in the following figure:

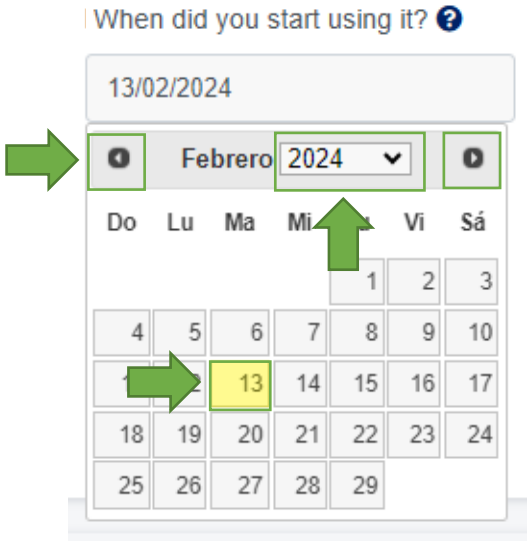
c) To answer the question **"How did you use the medication?" (dosage),** the patient should indicate in this space how they were taking the medication, for example: one tablet daily or 500 mg twice daily.



d) To declare the **Route of Administration** in which the medication was used, the patient must select one of the options presented from a drop-down list, as shown in the following figure:



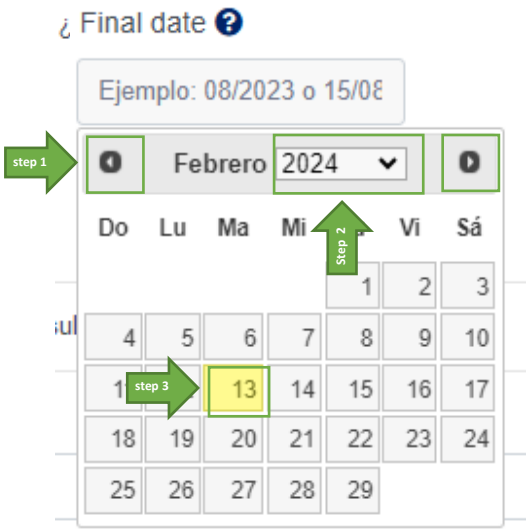
e) To answer the question **"When did you start using it?",** the patient should establish in as much detail as possible the date on which they began using the medication. To do this, the calendar shown below should be used:



You can use the drop-down calendar to make entering dates easier. To move between the different months of the year, just click the arrows in the top corners. To change the year, simply click on the current year text, which should display a list of available years. Simply select the corresponding year, then click on the day of the date you want to enter, and the date will automatically appear in the field in day/month/year format.

f) To answer the question **"What happened to the medication?",** the patient must define what happened with the use of the medication or vaccine administered after the suspected adverse reaction occurred. To do so, they must select one of the four options shown below:

- If the "**Discontinued"** option is selected, the patient must establish the exact date on which they stopped taking the medication. To do this, the calendar option shown below must be used.
  You can use the drop-down calendar to make entering dates easier. To move



between the different months of the year, just click the arrows in the top corners. To change the year, simply click on the current year text, which should display a list of available years. Simply select the corresponding year, then click on the day of the date you want to enter, and the date will automatically appear in the field in day/month/year format.

- If the option "**Discontinued *use and used again"*** is selected for this situation, the patient must answer the question whether a similar reaction has occurred again, selecting the option "**Yes"** or "**No"** as appropriate.
- ***Continue using"*** option, it establishes that the patient used the medication until the entire indicated treatment period was completed.

- If the option "**Dose *has been decreased"*** is selected, the patient must indicate the suggested modification by completing this information in the field called "Indicate quantity/frequency." To do this, indicate the way in which the medication was taken, for example: one tablet each day or 500 mg twice a day.

g) To complete the registration of the suspected adverse reaction medication, the patient must select the **"Accept and Save Medication**" button. This will save the suspected medication record, presented in the following format:

h) If any ***corrections to the information provided in the report are necessary,*** the patient can use the "Modify" option to make the necessary changes. Once the

modifications are complete, they must select the " **Modify medication information**" button.

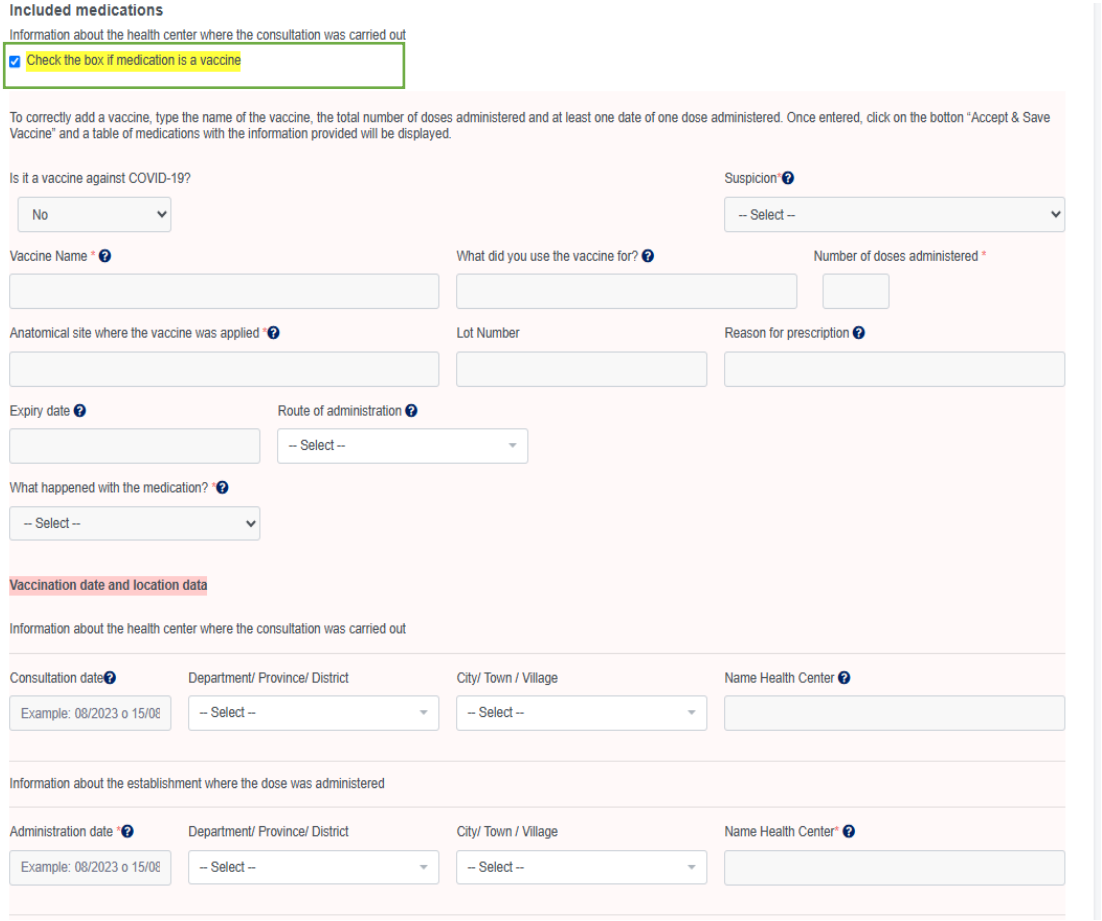
i) **Health Center Information Where the Consultation Was Made:** If the patient was consulted at a health center, please provide the following information:

- **Query date:** Specify the date in month/year or day/month/year format.
- **Department/ Province/ District:** A list of options will be displayed where you must select the department where the Health Center where the consultation was held is located.
- **City/ Town / Village:** The data in this list will depend on the department selected in the previous field and must indicate the municipality where the Health Center where the consultation was held is located.
- **Health Center Name,** enter the name of the health center where you received the medical consultation.

Report of a suspected ADR due to vaccines

If you wish to report an adverse reaction to a vaccine, you must follow the steps detailed below:

If the medication that caused the adverse reaction *is a vaccine, the box* **"Check the box if the medication is a vaccine"** must be checked; the following form will immediately be displayed.

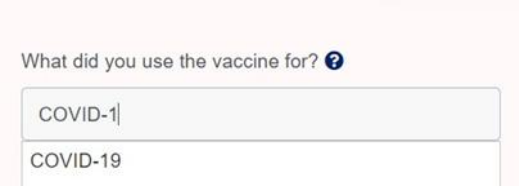


a) To answer the question: "**Is it a vaccine against COVID-19?"** The patient must answer Yes or No as appropriate.

b) To facilitate the "**Name of the vaccine"** (you can include the brand name) that may have caused the adverse reaction, several options will be displayed. These options will be filtered depending on whether the vaccine is for COVID or not.

If none of the options match the brand name of the vaccine you're looking for, you can freely type the name of the vaccine as you remember it.

c) To answer the question "**What did you use the vaccine for?"** enter the use for which the vaccine was indicated. As you type in this space, you can select one of the indications for use options from the drop-down list, as shown in the following figure:



d) To report the **Lot Number and Expiration Date** of the vaccine you are reporting, you can find this information on the medication packaging or the vaccination card. If it is not available or you do not know it, you can continue with the process of completing the information.

e) **"Number of doses administered",** indicate how many doses of the vaccine you are reporting have been administered to the patient, for example: 1, 2, 3, etc.

f) **"Anatomical site where the vaccine was applied",** indicate which part of the body received the vaccine dose that caused the reaction.

g) **"The dose that triggered the reaction"** refers to the specific amount of the vaccine administered. Examples: 0.3 ml, 0.5 ml, etc.

h) To answer the question **"What happened with the medication?"** define what happened with the use of the vaccine after the suspected adverse reaction occurred. To do so, select ***one of the four options*** shown below:

- **"It has been discontinued."**
- **"It stopped being used and then it was used again."**
- **Continue using"** option, it establishes that the patient used the medication until the entire indicated treatment period was completed.
- "**The dose has been reduced.**"

i) **Vaccination date and location data.** To correctly add the vaccine information, add the **Administration Date** and **Name of the Health Center** where the dose

was administered. You can also add information about where the consultation was made:

Health center information where the consultation was made: If the patient was seen at a health center, please provide the following information:

- **Query date:** Specify the date in month/year or day/month/year format.
- **Department/ Province/ District:** A list of options will be displayed where you must select the department where the Health Center where the consultation was held is located.
- **City/ Town / Village:** The data in this list will depend on the department selected in the previous field and must indicate the municipality where the Health Center where the consultation was held is located.
- **Health Center Name,** enter the name of the health center where you received the medical consultation.

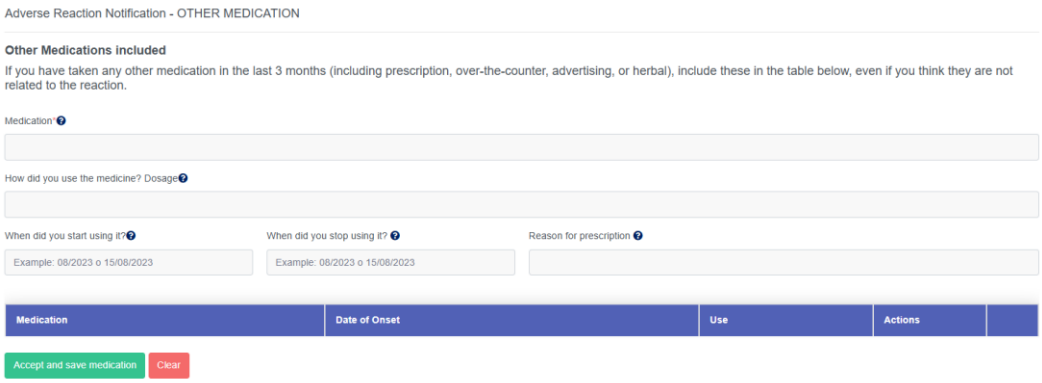
Information about the facility where the dose was administered: To save the dose data, the following information must be added:

- **Consultation date**: Specify the date of the patient's consultation and the date on which they received the vaccine dose. This information is required to add the dose to the vaccine.
- **Department/ Province/ District**: A list of options will be displayed where you select the department where the facility, that the dose was administered, is located.
- **City/ Town / Village**: The data on this list will depend on the department selected in the previous field and must indicate the municipality where the facility where the dose was administered is located.
- **Health Center Name**: The name of the facility where the vaccine dose was administered must be provided. This information is required to add the dose to the vaccine.

j) To complete the process, you must select the **"Accept and save vaccine"** button and then click the **"Next"** button.

Data on other medications

For step 3 of 5, called "**Other Medication Information**," if the patient has taken any other medication in the last 3 months (including prescription, non-prescription, branded, or herbal medications) even if you think they are not related to the reaction, you must include them in the following form:



a) **"Medication",** to facilitate the information on the name of the medication, as you type in this space, you can select the name of the active ingredient of the medication from the drop-down list, as shown in the following figure:

b) To answer the question **"How did you use the medication?" (dosage),** the patient should indicate how they were taking the medication, for example: one tablet daily or 500 mg twice daily.

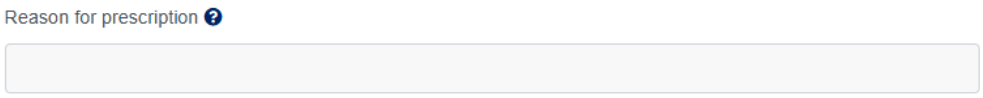
c) To answer the question **"When did you start using it?",** the patient should establish in as much detail as possible the date they started using the medication. To do this, they can use the month/year of starting medication format.

You can use the drop-down calendar to make entering dates easier. To move between the different months of the year, just click the arrows in the top corners. To change the year, simply click on the current year text, which should display a list of available years. Simply select the corresponding year, then click on the day of the date you want to enter, and the date will automatically appear in the field in day/month/year format.

d) To answer the question **When did you stop using it?** The patient must establish the exact date on which they stopped taking the medication. To do so, they can use the month/year format for stopping medication use.

You can use the drop-down calendar to make entering dates easier. To move between the different months of the year, just click the arrows in the top corners. To change the year, simply click on the current year text, which should display a list of available years. Simply select the corresponding year, then click on the day of the date you want to enter, and the date will automatically appear in the field in day/month/year format.

e) To answer the question **"Reason for prescription"** the patient must enter the use for which the medication was prescribed. As you type in this space, you can select one of the options from the drop-down list, as shown in the following figure:



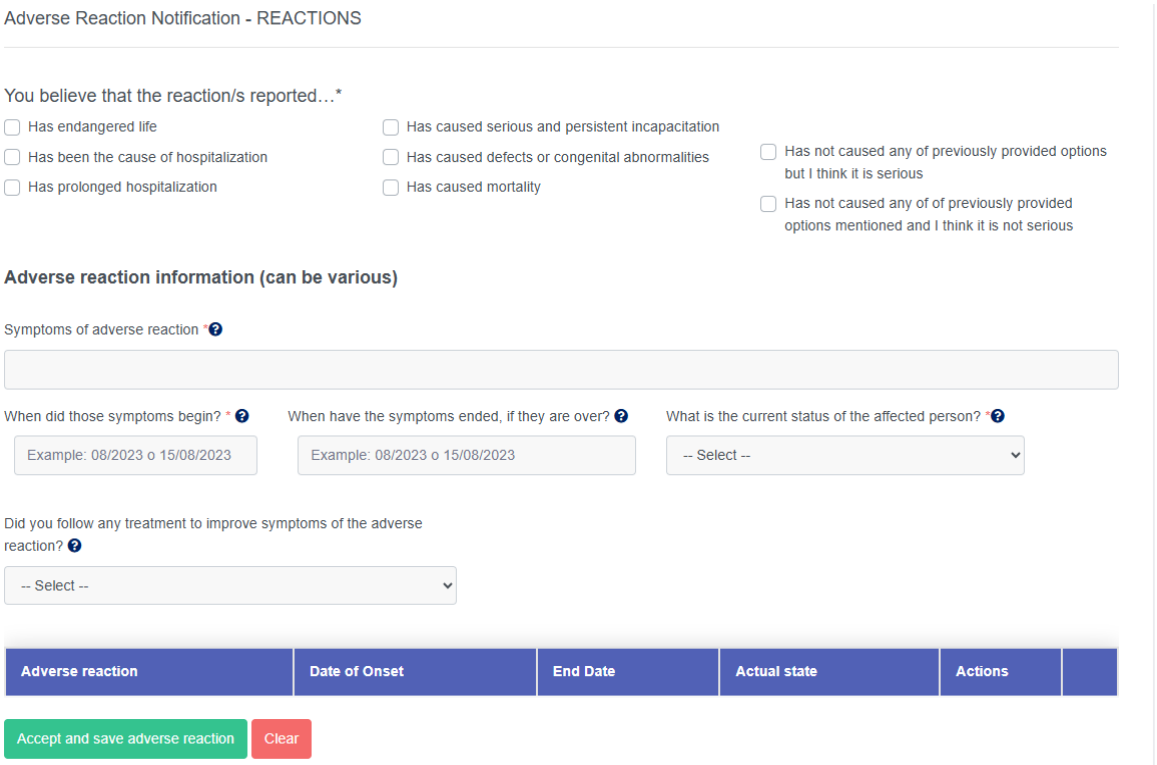
Once the form has been completed, click the **"Accept and Save Medication"** button. This will save the medication information to the table as follows:

If any corrections are necessary, the patient can use the **"Modify"** option to make the necessary changes. Once the changes are complete, they must select the "**Modify medication information**" button.

Once all the medications have been added in this section, click on "**Next**".

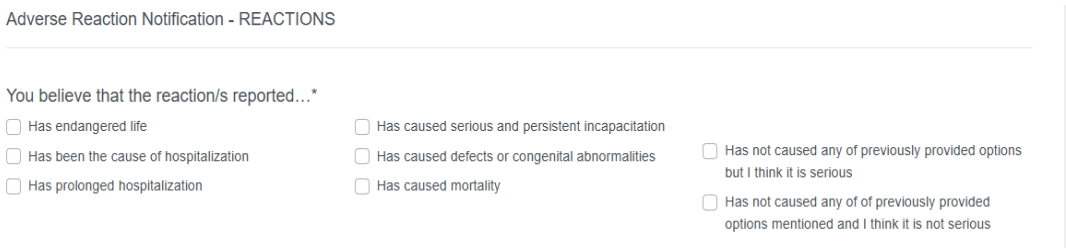
Reaction Information

For step 4 of 5, called "**Reaction(s) Information**", related to the necessary information on possible adverse reactions that have been identified by the patient and that are presumably linked to the medications he or she is using, the following information must be completed:



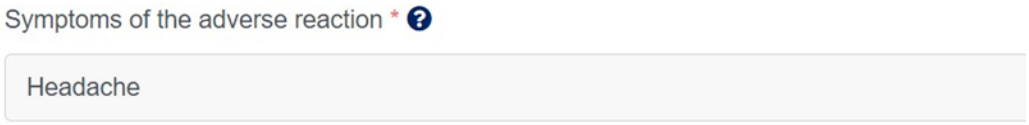
a) The patient, according to the status of the adverse reaction he has presented, must select one or more of the criteria shown in the following figure:

Please note that this is a field marked (*) which corresponds to mandatory information.



In the field called **"Adverse Reaction",** the adverse reaction that has occurred with the use of the medication(s) used by the patient must be entered. As one types in

this space, select the medical terminology that most closely matches the drop-down list, as shown in the following figure:



b) To complete the information related to **"When did those symptoms begin?",** first establish the date the adverse reaction occurred in as much detail as possible. For this, use the calendar format. The date must be reported in day/month/year format.

   Use the drop-down calendar to make entering dates easier. To move between the different months of the year, just click the arrows in the top corners. To change the year, simply click on the current year text, which should display a list of available years. Simply select the corresponding year, then click on the day of the date you want to enter, and the date will automatically appear in the field in day/month/year format.

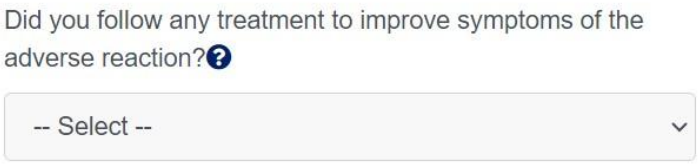
c) Next, provide the **"When have the symptoms ended, if they are over?"** information for the adverse reaction. For this information, the patient must establish the exact date on which the symptoms disappeared, if any, using a calendar format. The date must be reported in day/month/year format.

   Use the drop-down calendar to make entering dates easier. To move between the different months of the year, just click the arrows in the top corners. To change the year, simply click on the current year text, which should display a list of available years. Simply select the corresponding year, then click on the day of the date you want to enter, and the date will automatically appear in the field in day/month/year format.

d) To answer the question **" What is the current status of the affected person?"** at the time of reporting, select one of the options shown in the drop-down menu, as shown below:

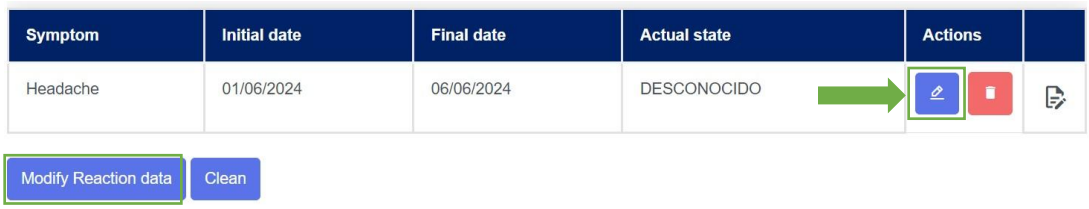
Please note that this is a field marked (*) that corresponds to mandatory information.

e) To answer the question, **"Did you follow any treatment to improve symptoms of the adverse reaction?",** select one of the options below. If you have not received any treatment, select "No treatment".



f) To complete the recording of adverse reaction data, the patient must select the **"Accept and save adverse reaction"** button**.** This action will save the adverse reaction record, presented in the following format:

g) If any corrections are necessary, the patient can use the modify option to make the necessary modifications. Once the modifications are complete, the patient must select the **"Modify Reaction Data"** button.



Notifier information

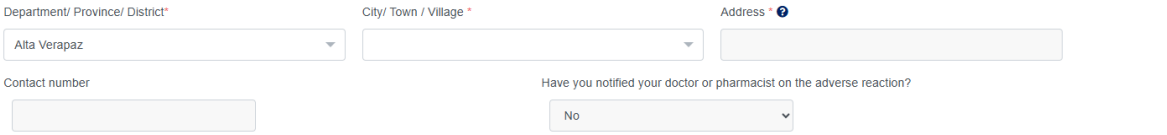
For step 5 of 5, this corresponds to the so-called "**Notifier Information**", in this section the general information of the person making the notification is detailed, and the following steps must be followed:

a) **Noti-FACEDRA** electronic form, it will be completed with the **name and surname of the notifier.**

Please note that this is a field marked (*) that corresponds to mandatory information.

b) **"Email"** address, which will be used to send the acknowledgement of receipt of the notification. To do this, confirm the email address, as shown in the following figure: Please note that this field is marked (*) and corresponds to mandatory information.

c) The notifier must provide a residential address so that they can be contacted in case more information is required regarding the reported case, including the details of the department/province, municipality of the country of notification, and must select one of the options shown in the drop-down menu, as well as a telephone number, as shown in the following figure:



d) To answer the question**: "Have you notified your doctor or pharmacist of the adverse reaction?"** Select **"Yes"** if it has already been done, or otherwise, select "**No**". If there is no information, select "**Don't know**".

e) If you have notified your physician and are willing to give your approval (consent) to contact your treating physician, click to activate the box that must be filled in with the necessary information to contact you if necessary, as shown in the following figure:

f) If more information related to the reported case can be provided, the patient can attach files to the report, as shown below:

In the field called "**Description of the file you want to attach**", provide a short description or the name of the file to be attached.

For the field called "**Path"**, select the file to be attached from the location (folder) on the device that is used to make the report.

Note: The supported formats for files attached to the notification are as follows:

- Text files of type .DOC,
- Image files of type .JPG, .GIF and type .PDF

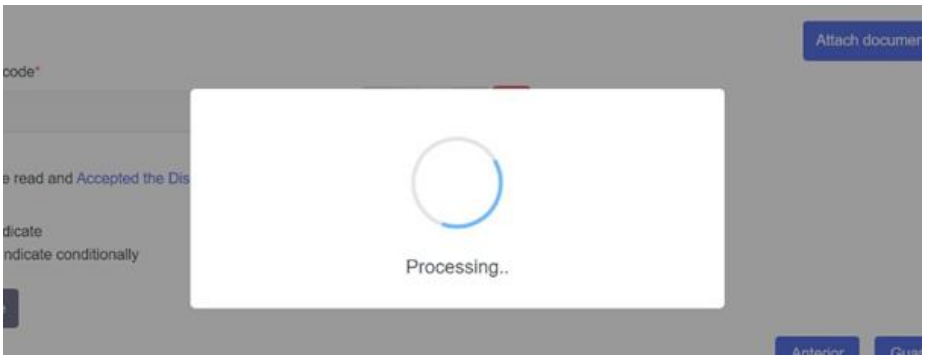
g) To upload as an attachment, click on the **"Add attachment"** button.

h) The notifier must enter the random key shown as an image in the field called "**Security Code",** as shown in the figure:

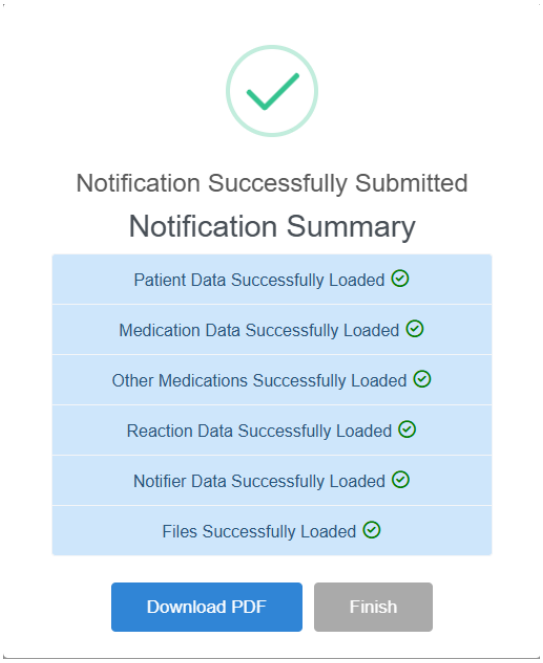
If it is not legible, the image can be updated by clicking on the button

i) For information security purposes, it is necessary for the notifier to select the option "I have read and accept the Legal Disclaimer "**I have read and accepted the terms of the legal notice**", which will display a window showing the text of the legal notice.

j) To complete the form and send the notification, click the **"Accept"** button. The platform will then display the following message:



k) Confirmation of submission of the form is presented as follows:



l) To print or download a copy of the report of notification of suspected adverse reactions that has been completed through **Noti-FACEDRA 2.1,** click on the "**Download PDF"** button and the process of downloading the file with the notification code in ***".PDF"*** format will begin, for example NCA11.PDF.

FACEDRA

ONLINE NOTIFICATION SYSTEM: NOTI-FACEDRA

Country: Costa Rica
Notification Number: NCA64349
Notification Date: 02/04/2025
Follow-up: No

PATIENT

Full Name: Rebeca Hernandez
Who experienced the adverse reaction?: Un familiar
Sex: Femenino
Age: Adulto
Weight (kg): 90.00
Height (cm): 158

Other reported illness:

#	Illness Name	Diagnosis Date
1	diabetes	02/2023

MEDICATION

Information about the medication that may have caused the adverse reaction

Suspected: Sospechoso
Type: Medicamento
Medication: **Acepress (IRBESARTAN) 150 mg TABLETAS (COMPRIMIDOS) Laboratorios Stein**
What is the medication used for?: Hipertensión(MedDRA)
Batch and expiration date: 123 12/2026
How was the medication used? (Dosage and posology): 1 tableta, 2 veces al dia
Route of administration: ORAL
What happened with the medication?: Sigue utilizándolo
Start date: 30/01/2025
End date:

translation: ¿Estaba embarazada en el momento de la medicación?: No
Query date: 30/01/2025
Health Center where consultation was made: clinica comunal

OTHER MEDICATION

If you have taken any other medication in the last 3 months (including prescription drugs,

Página 1 de 2

Sistema de Notificación en línea: Noti-FACEDRA, www.notificacentroamerica.net

FACEDRA

over-the-counter medications, advertised medicines, or herbal medicines), please include them in the table below even if you think they are not related to the reaction.

Type: Medicamento
Medication: **Metforal (METFORMINA HIDROCLORURO) 500 mg TABLETAS RECUBIERTAS CON PELÍCULA (COMPRIMIDOS RECUBIERTOS CON PELÍCULA) Laboratori Guidotti**
What is the medication used for?: Diabetes(MedDRA)
How was the medication used? (Dosage and posology): 1 al dia
Start date: 02/2023
End date:

REACTIONS

Reported reactions...
Has not caused any of of previously provided options mentioned and I think it is not serious

Information about the adverse reaction (there may be multiple)

Indicate the symptoms that made you suspect an adverse reaction: Urticaria(MedDRA)
Start date: 30/01/2025
End date: 08/02/2025
What is the current condition of the affected person?: EN RECUPERACIÓN / EN RESOLUCIÓN
Treatment: Farmacológico

Additional observations: uso de hidrocortisona topica una vez al día

NOTIFIER

Information about the person submitting the notification

Full Name: Rebeca Abigail DIAZ ORELLANA
Email: badekey995@flektel.com
Country: Costa Rica
Province/Department: Cartago
City/ Town / Village: La Unión
Workplace address: Frente a la Parroquia Nuestra Señora del Pilar
Contact phone: 22745000
Have you reported the adverse reaction to your doctor or pharmacist?: No
Contact consent: No

Página 2 de 2

Sistema de Notificación en línea: Noti-FACEDRA, www.notificacentroamerica.net

m) After downloading, the notifier will receive an acknowledgment of receipt to the email address included in paragraph b) of step 4 of 5, with a summary of the case, the case report code, and a unique key for possible follow-up or provision of further information. A sample of the acknowledgment of receipt is presented below:

Noti-FACEDRA <rbdo12002@gmail.com>
para mi

10:12 (hace 7 minutos)

SECRETARÍA EJECUTIVA COMISCA · SICA Sistema de la Integración Centroamericana · NOTI-FACEDRA PORTAL REGIONAL DE NOTIFICACIÓN EN LÍNEA DE SOSPECHAS DE REACCIONES ADVERSAS A MEDICAMENTOS DE USO HUMANO

Buen día,

Muchas gracias por notificar al ***Sistema Regional de Notificación en línea de Sospechas de Reacciones Adversas a Medicamentos:Noti-FACEDRA.***

Los datos del caso que ha notificado son los siguientes:
Número de Notificación: NCA64420
Contraseña: Sc30H1btApAb
Fecha notificación: 2024-01-15 10:12:45
Género del Paciente: Femenino
Edad del Paciente: 29 Año
Primer Fármaco sospechoso que notificó: CIPROFLOXACINO (2049A)
Primera Reacción adversa que notificó: Fiebre

Si en el futuro desea actualizar o rectificar la información enviada, deberá acceder de nuevo al formulario a través del Portal Regional de Notificación en línea Noti-FACEDRA:

Ir a Seguimiento de Noti-FACEDRA

Indicar que desea añadir información sobre un caso ya notificado e introducir el número de caso notificado y la contraseña proporcionados en este correo electrónico.

No es necesario que vuelva a incorporar toda la información del caso inicial aunque esta no aparezca en pantalla. Añada o rectifique únicamente la nueva información. Si fuera posible, en el campo Otros datos de interés que desee aportar comente la información añadida o rectificada.

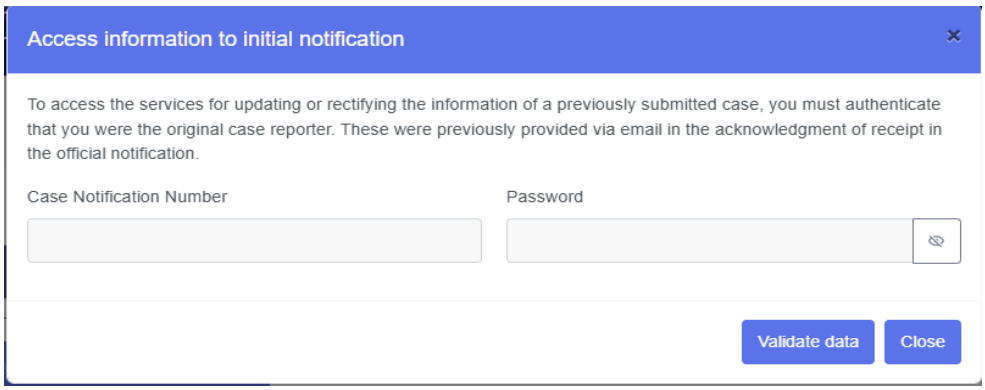
Contacto: Centro Nacional de Farmacovigilancia Guatemala, E-mail: farmacovigilanciadrcpfa@mspas.gob.gt

Follow -up of cases or provision of additional information on a reported case.

This section details the steps to be followed by the notifier if it is necessary to provide additional information on a reported case or if it is necessary to update or clarify the information provided in a previous notification. To do this, the notifier must do the following:

a) The person who reported the case and provided their contact information to receive the acknowledgment generated by **Noti-FACEDRA 2.1** should look for the following information in their email:
   I. Number of the reported case
   II. Individual password of the reported case.

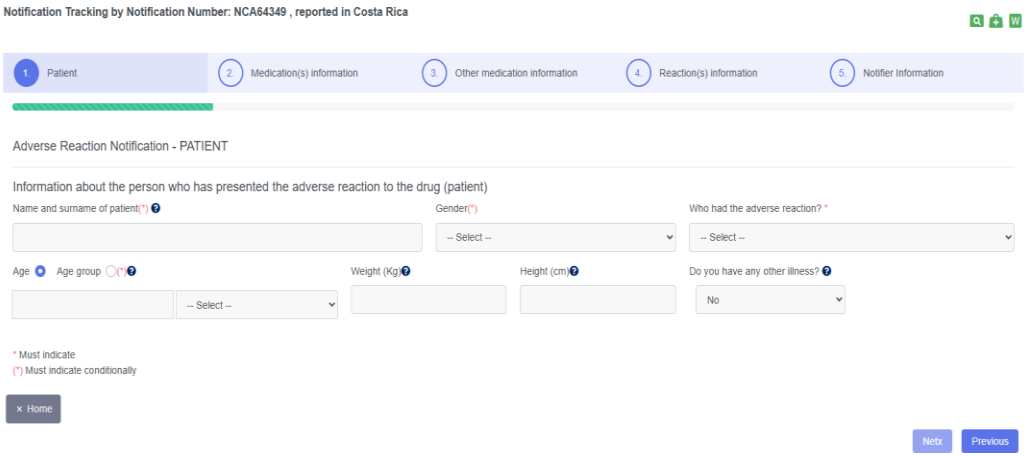
b) Once the information from step a) is available, the notifier must access **Noti-FACEDRA 2.1** through the link www.notificacentroamerica.net and click on **"Additional information on a case already notified"** where the following screen will be displayed:



In this space, you must enter the Notification Code and Password that you received in the acknowledgment email.

c) Upon entering the data, the report is accessed and the notifier can make changes or modifications to any of the fields in the form.

When accessing the form, all fields will be blank, as shown in the following figure:



Note: The notifier should only fill out the form with the information they wish to update or modify; the other fields on the form should be left blank.

d) If corrections or modifications to any of the steps in the form need to be made, ensure to select the "**Accept and Save**" button as appropriate.

e) To save any corrections or additional information you provide, click the "**Accept**" button. If the tracking was successful, a confirmation message will appear, giving the option to download the PDF again. Another email will also be sent to the notifier with your notification number and password.

Frequently Asked Questions

1. **If all medications can cause adverse reactions, does this mean that no medication is safe?** No medication or vaccine is completely free from adverse reactions, but the benefits obtained from the medication outweigh its potential risks.

   Many adverse reactions are rare. In general, most people who use a medicine or vaccine do not experience any adverse reactions. Even adverse reactions described as common occur in only a small percentage of people who use the medicine.

2. **Since I started using the medication, I've noticed a number of new symptoms that I think may be due to the medication. What should I do?** If you're concerned about a suspected adverse reaction, you should discuss it with your doctor or pharmacist. If you think a medication, vaccine, or herbal medicine has caused an adverse reaction, discuss it with your doctor or pharmacist.
   If you wish to report it directly, please complete the electronic **Noti-FACEDRA form** available at www.notificacentroamerica.net .

   When deciding whether the medication or vaccine you received could have caused the symptoms you are experiencing, several factors must be taken into account. If symptoms begin after starting treatment with the new medication or vaccine, they could be related to its use, but this will not always be the case. Your symptoms may be related to a disease or medical problem you have, or they may simply be a coincidence, especially if you have symptoms that commonly affect a large number of people in the population, for example, headaches.

   It's also possible that symptoms could be the result of an interaction between the new medication or vaccine you received and another medication you're using, or even a certain food.

   If your symptoms disappear when you stop using the medication, this may suggest that they were likely caused by the medication.

   Your doctor is in the best position to advise you about the symptoms you're experiencing, whether or not they're associated with the medication you're taking. They'll even tell you how to avoid some potential adverse reactions.

3. **What will happen to the notification I just completed?** Notifications are collected and uploaded to a specialized database that allows for rapid analysis and evaluation by the relevant national authorities.

Your notification will be considered in the context of all other notifications received from patients or healthcare professionals. The Medicines Regulatory Authority in your country may use your notification in several ways:

- Conduct a targeted analysis of similar notifications to identify new information on drug safety.
- Consider the patient's perspective to better understand the impact of adverse reactions on people who use medications.
- Request additional information from other sources.
- Discuss the adverse reaction with the other Drug Regulatory Authorities in Central America and the Dominican Republic to take joint action to address these potential problems.

4. **Is my notification really important?** Yes, it is. It helps to better understand the actual use of medications and vaccines used in the private and public sectors in SICA Member States, contributing to the safe use of medications by the population. We need this data to identify new adverse reactions or conditions in which they occur; this will help reduce the risk of medication use and thus optimize treatments.

5. **What happens to my personal information in the notification I just completed?** Your personal data is managed anonymously and is not incorporated into the adverse reaction database. Only the patient's sex and age are processed. The confidentiality of your data is expressly protected by current legislation, and it will not be transmitted to any person or organization outside the National Pharmacovigilance Center of your country.

6. **If I fill out a form, will my doctor or other healthcare professional receive a copy?** No, under no circumstances. Once the notification is sent, only you will receive a copy of the report and your ID number.

SECRETARÍA EJECUTIVA
COMISCA
CONSEJO DE MINISTROS DE SALUD DE CENTROAMÉRICA Y REPÚBLICA DOMINICANA

SICA
Sistema de la Integración Centroamericana

"Solidaridad entre los pueblos para la integración regional en salud"

@SECOMISCA Se-Comisca SICA Secretaría Ejecutiva del COMISCA

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