PACKAGE LEAFLET: INFORMATION FOR THE USER

INALGEX, 50 mg/g, Gel
INALGEX, 100 mg/g, Gel
INALGEX, 100 mg/ml, Cutaneous emulsion
INALGEX, 100 mg/ml, Cutaneous spray, solution
Etofenamate

Read all of this leaflet carefully because it contains important information for you.
This medicine is available without prescription. However, you still need to use Inalgex carefully to get the best results from it.
Keep this leaflet. You may need to read it again.
Ask your pharmacist if you need more information or advice.
You must contact a doctor if your symptoms worsen or do not improve after two weeks.
If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT INALGEX IS AND WHAT IT IS USED FOR

Inalgex contains etofenamate, which is a non-steroidal anti-inflammatory drug, to apply on the skin, directly on the painful area, and that acts on:
pain relieve;
swelling and inflammation reduction.

Inalgex can be used by adults in the treatment of:
muscular and joints injuries, such as contusions, strains, sprains and tendinitis;
rheumatic diseases (rheumatism), such as arthritis and arthrosis.

Inalgex is a medicine for external use, for application on the skin, which cannot be applied on eyes or mucosas.

2. BEFORE YOU USE INALGEX

Do not use INALGEX
if you are allergic (hypersensitive) to etofenamate or any of the other ingredients of Inalgex (see Further Information); if you are pregnant; in the injured and infected skin,

which includes areas of the skin with wounds and eczema (a type of skin inflammation); in children aged less than 12 years old.

Before you apply Inalgex, check with your doctor or pharmacist if this medicine is adequate for your situation.

Since Inalgex is applied on the skin, directly on the painful area, there is a risk of absorption into the bloodstream, with the appearance of effects in other parts of the body besides the application site. The risk of occurrence of these effects is minimal and depends, among other things, of the exposed surface, the amount applied and time of exposure.

Take special care with INALGEX
if you are allergic (hypersensitive) to other non-steroidal anti-inflammatory drugs for skin application;
if you expose the area where Inalgex was applied to sunlight, since photosensitive dermatitis may appear (it is a skin inflammation that can manifest itself by redness and itching at the application site after sun exposure). If you feel one of these symptoms, contact immediately your doctor or pharmacist;
if the application area is near mucosas (for example mouth) or eyes;
if you have liver or kidney problems.

Using other medicines
There is a chance Inalgex may alter the effect of other medicines that you are taking. For that to happen, it is necessary that Inalgex, applied on the skin, is absorbed into the bloodstream. Since Inalgex is absorbed in insignificant quantities into the bloodstream, it is very unlikely that it interferes with other medicines.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

If you are taking any of the following medicines, contact your doctor or pharmacist before you begin the application of Inalgex because it may compromise its effect or increase the risk of side effects:

Medicines used to control the blood pressure, including diuretics;
Medicines used to make blood thinner;
Lithium, used in the treatment of bipolar disease.

Pregnancy and breast-feeding
Ask your doctor or pharmacist for advice before taking any medicine.

Inalgex cannot be used if you are pregnant or think you may be pregnant.
Inalgex can be used by women breastfeeding.

Driving and using machines

It is not expected that the use of Inalgex affects your ability to drive and use machines.

Important information about some of the ingredients of INALGEX
Inalgex, 100 mg/ml, Cutaneous emulsion contains cetyl alcohol (excipient). May cause local skin reactions (e.g. contact dermatitis).
Inalgex, 100 mg/ml, Cutaneous spray, solution contains propylene glycol (excipient). May cause skin irritation.

3. HOW TO USE INALGEX

Always use Inalgex exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Wash your hands before each application and after each application, except if the painful area is on the hands.
This medicine is meant for skin application, directly on the painful area, every time there is not any wound on that area.

Inalgex, 50 mg/g, Gel
Use about 5 to 10 cm of gel in each application.
The application must be done on all the painful area, spreading the gel resorting to smooth friction.

Inalgex, 100 mg/g, Gel
Use about 2.5 to 5 cm of gel in each application.
The application must be done on all the painful area, spreading the gel resorting to smooth friction.

Inalgex, 100 mg/ml, Cutaneous emulsion
Use about 1.5 to 2.5 ml or a quantity of about 3 cm of diameter of cutaneous emulsion in each application.
The application of the cutaneous emulsion must be done on all the extension of the painful area.

Inalgex, 100 mg/ml, Cutaneous spray, solution
Press the dispenser to apply 3 to 5 jets per application.
The application of the cutaneous spray, solution must be done on all the extension of the painful area.

Inalgex must be used by adults in the following way:

Treatment of muscular or joints injuries, like contusions, strains, sprains and tendinitis	3 to 4 Inalgex applications daily, for 14 days
Treatment of rheumatic diseases (rheumatism), like arthritis and arthrosis	2 to 3 Inalgex applications daily

You should feel a pain and/or inflammation relieve after 3 or 4 days of treatment with Inalgex.

Do not use Inalgex more than 14 days in case of muscular or joints injuries, or 21 days for arthritis and arthrosis pains, unless your doctor tells you otherwise.

You must contact a doctor if your symptoms worsen or do not improve after 7 days.

If you have liver or kidney problems talk to your doctor because he might want to adjust the Inalgex applications.

In case of accidental contact with INALGEX
Do not apply Inalgex in the injured or infected skin.
If you verify accidental contact with the eyes, mucosas (for example mouth) or areas of injured skin, wash abundantly the affected area with running water. If the irritation persists contact your doctor or pharmacist.

In case of accidental or deliberate intake of INALGEX
Immediately go to a hospital where the adequate therapeutic measures should be implemented. Take the package and the tube or the bottle with you.

If you use more INALGEX than you should
There are no known situations of Inalgex overdose when a quantity higher than the recommended of gel or of cutaneous spray, solution is applied on the skin.

If you forget to use INALGEX
Do not worry if, occasionally, you forget to apply Inalgex. In these situations, continue the applications as usual, in the usual schedule.

If you stop using INALGEX
The treatment can be stopped at any time, without requiring special care. However, you may feel pain or swelling in the affected area again.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Inalgex can cause side effects, although not everybody gets them.

You should stop the treatment with Inalgex immediately and contact your doctor immediately if you notice the following side effects:
Hipersensivity, which is a kind of allergic reaction manifested by cutaneous rash (skin eruption with redness), shortness of breath and difficulty swallowing;

Bullous conditions (extensive changes on the skin with redness, scaling and large blisters).
Photosensitive dermatitis (skin inflammation that can manifest itself by redness and itching at the application site after sun exposure).

Apparently the risk of occurrence of these reactions is greater at the beginning of the treatment and, in most cases, these reactions happen during the first month of treatment.

The following side effects may occur, described in accordance with its frequency:

Common (affects 1 to 10 users in 100)
Pruritus (itching);
Erythema (appearance of reddish areas on the skin);
Local skin irritation, that usually disappears when the treatment is stopped.

Rare (affects 1 to 10 users in 10,000)
Contact dermatitis (inflammation of the skin in the application area);
Allergic dermatitis (skin inflammation due to allergy to Inalgex);
Photosensitive dermatitis (skin inflammation that can manifest itself by redness and itching at the application site after sun exposure).

Very rare (affects less than 1 user in 10,000)
Hives (skin rash with itching);
Bullous conditions (extensive changes at the skin with redness, scaling, and large blisters) that can include:
Stevens-Johnson syndrome;
toxic epidermal necrolysis.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE INALGEX

Keep out of the reach and sight of children.
Inalgex, 50 mg/g, Gel
Store below 25ºC.

Inalgex, 100 mg/g, Gel
This medicinal product does not require any special temperature storage conditions.
Store in the original package in order to protect from light.
After the first opening use the medicinal product in a maximum period of 6 months.

Inalgex, 100 mg/ml, Cutaneous emulsion
This medicinal product does not require any special temperature storage conditions.
Store in the original package in order to protect from light.

After the first opening use the medicinal product in a maximum period of 6 months.

Inalgex, 100 mg/ml, Cutaneous spray, solution
This medicinal product does not require any special temperature storage conditions.
Store in the original package in order to protect from light.
After the first opening use the medicinal product in a maximum period of 6 months.

Do not use Inalgex after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of the month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What INALGEX contains
The active substance is etofenamate.

Inalgex, 50 mg/g, Gel
Each 100 g of Inalgex, 50 mg/g, Gel contain 5 g of etofenamate.
The other ingredients of Inalgex, 50 mg/g, Gel are: ethanol, glycerol, trolamine, purified water and carbopol.

Inalgex, 100 mg/g, Gel
Each 100 g of Inalgex, 100 mg/g, Gel contain 10 g of etofenamate.
The other ingredients of Inalgex, 100 mg/g, Gel are: isopropyl alcohol, glycerol, trolamine, purified water and carbopol.

Inalgex, 100 mg/ml, Cutaneous emulsion
Each 200 ml of Inalgex, 100 mg/ml, Cutaneous emulsion contain 20 g of etofenamate.
The other ingredients of Inalgex, 100 mg/ml, Cutaneous emulsion are: cetyl alcohol, macrogol stearate, glyceryl monostearate, benzyl alcohol, sodium citrate dihydrate, anhydrous citric acid, aluminium and magnesium silicate, diisopropyl adipate, purified water.

Inalgex, 100 mg/ml, Cutaneous spray, solution
Each 200 ml of Inalgex, 100 mg/ml, Cutaneous spray, solution contain 20 g of etofenamate.
The other ingredients of Inalgex, 100 mg/ml, Cutaneous spray, solution are: propylene glycol, macrogol cetostearyl ether, macrogol 400, diisopropyl adipate, isopropyl alcohol and purified water.

What INALGEX looks like and contents of the pack
Inalgex, 50 mg/g, Gel is presented as an aluminium tube containing 100 g of gel.

Inalgex, 100 mg/g, Gel is presented as an aluminium tube containing 100 g of gel.
Inalgex, 100 mg/ml, Cutaneous emulsion is presented as a high density polyethylene bottle with dispenser containing 200 ml of cutaneous emulsion.
Inalgex, 100 mg/ml, Cutaneous spray, solution is presented as a high density polyethylene bottle with dispenser containing 200 ml of cutaneous spray, solution.

Marketing Authorisation Holder and Manufacturer

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For any information about this medicine, please contact the Marketing Authorisation Holder.

This leaflet was last approved in