APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S1

Reparil®-Gel

Aescin and Diethylamine salicylate

Read all of this leaflet carefully before you start using Reparil-Gel

Always take this medicine exactly as described in this package leaflet or as your doctor or pharmacist has told you.

Keep this leaflet. You may need to read it again later.

Ask your pharmacist if you need more information or advice.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

You must contact a doctor if you do not feel better or if you feel even worse after two days.

What Reparil-Gel is and what it is used for

What you need to know before you use Reparil-Gel

1. **How to use Reparil-Gel**
2. **Possible side effects**
3. **How to store Reparil-Gel**
4. **Contents of the pack and other information**

1. What Reparil-Gel is and what it is used for

Reparil-Gel eases the pain from sprains and bruising that may occur in sport or other injuries. The gel also temporarily relieves minor pain and stiffness experienced with rheumatism and muscle soreness.

2. What you need to know before you use Reparil®-Gel

Do not use Reparil-Gel:

if you are hypersensitive (allergic) to salicylate and/or aescin as well as to dlimonene, farnesol and linalool – constituents of lavender oil and neroli oil/ orange bitter flower oil -, or to any of the other ingredients of Reparil-Gel (listed in section 6), or if you have had hypersensitive (allergic) reactions to other analgesics and anti-rheumatics (non-steroidal anti-rheumatic agents).

on open wounds, inflammations or infections of the skin, and eczemas or on mucous membranes and skin areas which have been exposed to radiotherapy.

Warnings and precautions

Special care is required when using Reparil-Gel:

• if you suffer from asthma, hay fever, swelling of the nasal mucosa (so-called nasal polyps) or chronic obstructive respiratory tract diseases or chronic respiratory tract infections (particularly in combination with hay fever-like symptoms) and if you are hypersensitive (allergic) to analgesics and anti-rheumatics of any kind, you are at a greater risk by asthma attacks (analgesic intolerance/analgesic asthma), local skin and mucosal swelling (Quincke's edema) or urticaria than other patients.

- if you have hypersensitive (allergic) reactions to other substances, e.g. skin reactions, itching or urticaria.

• in acute conditions involving pronounced reddening, swelling or overheating of joints, in cases of persisting or worsening complaints. In these cases you should consult a doctor.

• Reparil-Gel contains as fragrances lavender oil and neroli oil/bitter orange flower oil with d-limonene, farnesol and linalool. These substances may cause allergic reactions.

• Reparil-Gel must not get into contact with your eyes.

• Children’s hands should not get into touch with skin areas treated with the medicine.

If you need advice about the above conditions, contact a healthcare professional.

Other medicines and Reparil-Gel

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

No interactions have become known to date for Reparil-Gel if used as directed.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before you use Reparil-Gel.

No data on the use of Reparil-Gel in pregnant women are available. Therefore, the use of Reparil-Gel during pregnancy is not recommended. Especially, application on a large area should be avoided.

It is not known if the ingredients of Reparil-Gel pass into human breast milk.

Therefore, the application of Reparil-Gel during breast-feeding is not

recommended, in particular its application in the breast area must be avoided.

Driving and using machines

Reparil-Gel has no or negligible influence on the ability to drive and use machines.

3. How to use Reparil®-Gel

Do not share medicines prescribed for you with any other person. This gel is for applying to the skin and must not be swallowed. Do not apply to broken skin and very raw areas. Avoid getting the gel into the eyes. If this happens, rinse thoroughly with water. Apply a thin layer of gel to the affected area once or several times daily. It is not necessary to rub and gel in. If you do not get relief within 2 days, consult a healthcare professional.

If you use more Reparil-Gel than you should In the event of overdosage, consult your doctor or pharmacist. If neither is available, rush to the nearest hospital or poison control centre.

4. Possible side effects

Reparil-Gel can have side effects.

Not all side effects reported for Reparil-Gel are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using Reparil-Gel, please consult your health care provider for advice. If any of the following happens, stop using Reparil-Gel and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious

reaction to Reparil-Gel. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Diseases of the skin and subcutaneous tissue disorders:

Frequent: Dehydration of the skin, eczema including pustule or wheal formation, reddening of the skin (erythema), inflammation of the skin (dermatitis, including contact dermatitis), itching (pruritus), nettle rash (urticaria), scaling.

Other possible side effects:

If Reparil-Gel is applied on large areas of the skin, the occurrence of systemic side effects affecting a specific organ system (e.g. hepatic, renal or gastro-intestinal side effects) or even the entire organism (e.g. hypersensitivity reactions, asthma) as they may appear after the intake of medicines containing salicylate, cannot be excluded. Reparil-Gel contains as fragrances lavender oil and neroli oil/bitter orange flower oil with d-limonene, farnesol and linalool. These substances may cause allergic reactions.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reactions & Quality Problem Reporting Form”, found online under SAHPRA’s publications:

https://sahpra.org.za/wpcontent/uploads/2020/01/6.04_ARF1_v5.1_27Jan2020.pdf

By reporting side effects, you can help provide more information on the safety of Reparil-Gel.

5. How to store Reparil-Gel

Store all medicines out of reach of children.

- Store at or below 25 °C. Keep the tube well closed.
- Store Reparil-Gel in a cool dry area out of direct sunlight.
- Do not use after the expiry date stated on the label or carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

Reparil-Gel contains

- The active substances per 100 g:

Aescin (Horse Chestnut) 1,0 g

Diethylamine salicylate 5,0 g

- The other ingredients are disodium edetate, carbomer 980, macrogol-6-glycerol caprylocaprate, trometamol, isopropanol, lavender oil, neroli oil/bitter orange flower oil, purified water.

What Reparil-Gel looks like and contents of the pack

Reparil-Gel is a pale yellow, clear gel which is non-greasy, non-staining and has a pleasant herb smell.

Contents of the pack:

Reparil-Gel comes in plastic tubes of 20 g, 40 g and 100 g.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

To be confirmed.