APPROVED PROFESSIONAL INFORMATION

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

Reparil®-Gel

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

100 g contains:

Aescin 1,0 g

Diethylamine salicylate 5,0 g

Excipients with known effects:

Lavender oil and neroli oil/orange bitter flower oil with d-limonene, farnesol and linalool.

For the full list of excipients, see section 6.

3 PHARMACEUTICAL FORM

Gel.

A transparent, pale yellow, non-greasy, non-staining, alcohol-based gel with a characteristic odour

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Symptomatic relief of pain associated with superficial soft tissue injuries, such as certain sports injuries.

Provides temporary relief from the minor pain and stiffness of rheumatism and muscle soreness.

4.2 Posology and method of administration

Posology

Unless otherwise directed, a thin layer of the gel should be applied to the skin over the affected area several times daily.

Method of administration

For topical use.

4.3 Contraindications

Reparil-Gel must not be applied:

• in patients with a history of hypersensitivity to the active substance salicylate and/or aescin, as well as to d-limonene, farnesol and linalool – constituents of lavender oil and neroli oil/orange bitter flower oil -, or to any of the excipients of the medicine listed in section 6.1 or other analgesics and anti-rheumatics (non- steroidal anti-rheumatics).

• on open wounds, inflammations or infections of the skin or to eczemas and mucousmembranes as well as areas of the skin that have been exposed to radiation treatment. (1)

For use of Reparil-Gel during pregnancy and lactation, see section 4.6.

4.4 Special warnings and precautions for use

Due to its alcohol content, Reparil-Gel should not be applied to areas of eczema or ulceration, not to skin exposed to therapeutic irradiation, but only to the surrounding parts in order to avoid a possible burning sensation.

When using Reparil-Gel, patients suffering from asthma, hay fever, swelling of the nasal mucosa (so-called nasal adenoids) or chronic obstructive respiratory tract diseases or chronic respiratory tract infections (particularly in combination with hay fever-like symptoms) and patients with hypersensitivity to analgesics and anti-rheumatics of any kind are at a greater risk than other patients by asthma attacks (so-called analgesic intolerance and analgesic asthma), local skin or mucosal swelling (so-called Quincke's oedema) or urticaria.

In these patients, Reparil-Gel may only be used when specific precautionary measures are taken, and direct medical supervision is performed. The same applies to patients who also react allergically to other substances, e.g. with cutaneous reactions, pruritus or urticaria.

In acute conditions involving pronounced reddening, swelling or overheating of joints with persisting or worsening complaints, a doctor should be consulted.

Reparil-Gel must not get into contact with the eyes.

Paediatric population

Children's hands should be ensured not to get in touch with skin areas treated with Reparil-Gel.

Excipients

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.

4.5 Interaction with other medicines and other forms of interaction

No interactions have become known to date for Reparil-Gel if used as directed.
Nevertheless, the treating medical practitioner should be informed which medicines are used at the same time and/or have been used recently.

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4.6 Fertility, pregnancy and lactation

No data are available on the use of Reparil-Gel in pregnant women. No adequate animal experimental studies on the reproductive toxicity of the ingredients of Reparil-Gel are available (see section 5.3).
Use of Reparil-Gel during pregnancy is therefore not recommended. Particularly application on a large area should be avoided.

It is not known if the ingredients of Reparil-Gel pass into human breast milk. Animal experimental studies on ingredients passing into breast milk are not available. Therefore, the use of Reparil-Gel during breast-feeding is not recommended. In particular, its application in the breast area must be avoided.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

The following convention has been used for the classification of side effects in terms of frequency:

Very common: ≥ 1/10

Common: ≥ 1/100 to < 1/10

Uncommon: ≥ 1/1,000 to < 1/100

Rare: ≥ 1/10,000 to < 1/1,000

Very rare: < 1/10,000

Not known: Frequency cannot be estimated from the available data.

Skin and subcutaneous tissue disorders:

Very rare: Dehydration of the skin, eczema including pustule or wheal formation, erythema, dermatitis (including contact dermatitis), pruritus, urticaria, scaling.

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 systemic use of medicines containing salicylate, cannot be excluded.

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Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions 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

4.9 Overdose

Systemic poisoning may occur from application to very large areas of skin.

If the recommended dose for cutaneous application is exceeded, the gel should be removed and rinsed off with water. If considerably excessive amounts are applied or Reparil-Gel has been ingested inadvertently, a medical practitioner should be contacted.

No specific antidote is available.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 13.9 Dermatological preparations – special combinations. Pharmacotherapeutic group: Non-steroidal antiphlogistic/analgesic, saponin, ATC Code: M02AC55.

Reparil-Gel has analgesic properties.

Salicylates belong to the group of non-steroidal antiphlogistics/analgesics that has proven effective in common animal experimental inflammation models by inhibition of prostaglandin synthesis. In humans, salicylates reduce inflammation-induced pain. Furthermore, salicylates reversibly inhibit ADP (adenosine-5'-diphosphate) and collagen-induced platelet aggregation. (1)

Aescin is a mixture of approximately 30 saponins. Characteristics attributed to saponins include anti-inflammatory properties. Even small amounts of saponins already exhibit haemolytic properties.

5.2 Pharmacokinetic properties

Following cutaneous application salicylate/aescin is probably absorbed in a dermal depot and slowly released from there to the central compartment. The percutaneous absorption rate (bioavailability) of salicylate, obtained from comparative studies (oral/local), comes to approximately 15 %.

The observed therapeutic efficacy is primarily explained by therapeutically relevant tissue concentrations of the medicinal product beneath the application site. In this respect the penetration to the site of action may differ, depending on the extent and nature of the affection as well as on the site of application and action.

5.3 Preclinical safety data

Animal experimental investigations on local tolerability were performed. (1)

Following daily applications to the dorsal skin over 4 weeks (rats, rabbits) and/or 12 weeks (pigs), no macroscopically or histologically specific local skin damage was detected.

Following single instillation into the conjunctival sac of rabbits, reversible low to high-grade inflammatory changes occurred in the conjunctiva. (1)

In humans, Reparil-Gel must therefore not be applied to mucous membranes or wounds (see section 4.3).

Reparil-Gel has not been sufficiently tested for reproductive toxicity. Fertility studies and investigations of postnatal effects of in utero exposure have not been carried out.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients Disodium edetate (Ph. Eur.) Carbomer 980

Macrogol-6-glycerol caprylocaprate (Ph. Eur.) Trometamol

Propan-2-ol (Ph. Eur.) Lavender oil

Neroli oil/Bitter orange flower oil

Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

5 years.

Shelf life after first opening of the container: 6 months

6.4 Special precautions for storage

Store at or below 25 ºC. Keep the tube tightly closed.

6.5 Nature and contents of container

Tubes of 20 g, 40 g and 100 g.

6.6 Special precautions for disposal and other handling

No special precautions required.

7 HOLDER OF CERTIFICATE OF REGISTRATION

[Viatris South Africa (Pty) Ltd

4 Brewery Street

Isando, Johannesburg,

1609]

8 REGISTRATION NUMBER

G/13.9/2367

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

23 August 2011

10 DATE OF REVISION OF THE TEXT

21 April 2021