

يجب التوقف عن إستعمال الدواء والتوجه فوراً إلى الطبيب إذا كنت تلاحظ:

- علامة أي رآكت من الحساسية بين المفضلة فيما يلي:
- طلع جلدي مع بثور (نادر - يمكن أن يظهر لدى 1-10 مستخدمين من بين 10,000) ; فرط الحساسية (بما في ذلك شرى) (نادر جدا - يمكن أن يظهر لدى أقل من واحد من بين 10,000).
- صغير، ضيق في التنفس أو شعور بضغط في الصدر (الربو) (نادر جدا - يمكن أن يظهر لدى أقل من واحد من بين 10,000).
- انتفاخ الوجه، الشفتين، اللسان أو الحلق (نادر جدا - يمكن أن يظهر لدى مستخدم واحد من بين 10,000).

أعراض جانبية إضافية:

أعراض جانبية شائعة (common)- الأعراض التي تظهر لدى 1-10 مستخدمين من بين 100 طلع جلدي، أكزيما، احمرار في الجلد، التهاب الجلد (بما في ذلك التهاب الجلد التماسي). حكة.*

أعراض جانبية نادرة جداً (very rare)- الأعراض التي تظهر لدى أقل من مستخدم واحد من بين 10,000. يمكن أن يكون الجلد أكثر حساسية للشمس. العلامات المحتملة هي حروق شمس مع حكة، تورم وبثور. طلع مع قيج.

أعراض جانبية ذات شوبوع غير معروف (الأعراض التي لم يتم تحديدها بعد)

- ردود فعل في منطقة البخ، جلد جاف، وشعور بحرقة.
- * في بحث سريري تم الإبلاغ عن حكة بثورات 0.9%، 236 متعالجين مع التواء الكاحل تمت معالجتهم مع 4-5 بخات من سويس رليف بخاخ جل 3 مرات يومياً (120 متعالج) أو بدواء وهمي

(116 متعالج) لمدة 14 يوماً.

إذا استعملت الدواء لفترة طويلة وأو تستخدم على مساحات كبيرة من الجلد، قد تظهر أعراضاً جانبية جهازية على سبيل المثال: الآم في البطن واضطرابات في الجهاز الهضمي، حرقة، مشاكل كبد أو كلى وتفاعلات فرط الحساسية.

إذا ظهرت أعراض جانبية، إذا كانت إحدى الأعراض الجانبية تتفاقم، أو إذا كنت تعاني من عرض جانبي لم يذكر في النشرة، يجب عليك استشارة الطبيب.

التبليغ عن أعراض جانبية:

يمكن التبليغ عن أعراض جانبية لوزارة الصحة بواسطة النقر على الرابط "الإبلاغ عن أعراض جانبية عقب علاج دوائي" الموجود في صفحة البيت من موقع وزارة الصحة (www.health.gov.il) الذي يوجه إلى نموذج الكتروني للتبليغ عن أعراض جانبية، أو عن طريق دخول الرابط: <https://sideeffects.health.gov.il>

بالإضافة، يمكن التبليغ لشركة باداجيس بواسطة العنوان التالي: Padagis.co.il

5. كيف تخزن الدواء؟

- تجنب التسمم! يجب حفظ هذا الدواء وكل دواء آخر في مكان مغلق بعيداً عن متناول أيدي الأطفال ومجال رؤيتهم وهكذا لتجنب التسمم. لا تسبب التقيؤ بدون تعليمات صريحة من الطبيب.
- لا يجوز استعمال الدواء بعد تاريخ انتهاء الصلاحية (exp. date) الذي يظهر على القارورة والعبوة. تاريخ انتهاء الصلاحية ينسب إلى اليوم الأخير من ذلك الشهر.
- خزنها في العبوة الأصلية ما دون 25°C.
- بعد الفتح لأول مرة يمكن الاستعمال لمدة 6 أشهر، ولكن ليس بعد تاريخ انتهاء الصلاحية.
- لا يجوز التخلص من الدواء في مياه الصرف

الصحي أو الغالبات المنزلية. استشر الصيدلي حول كيفية التخلص من الدواء. هذا سيساعد على حماية البيئة.

6. معلومات إضافية

إضافة للمادة الفعالة، يحتوي الدواء أيضاً على:

Purified water, Propylene glycol, Isopropylene alcohol, Soy bean lecithin 76%, Ethanol (anhydrous), Disodium phosphate dodecahydrate, Peppermint oil, Sodium dihydrogen phosphate dihydrate, Disodium edetate, Ascorbyl palmitate, Hydrochloric acid, Sodium hydroxide

كيف يبدو الدواء وما هو محتوى العبوة:

قارورة زجاجية بنية اللون داكنة ذات فوهة بخ، يحتوي على محلول بلون أصفر-ذهبي شفاف، حيث إن ملمسه بعد الرش يشبه الجل. متوفر بحجم تعبئة 25 غرام.

صاحب التسجيل وعنوانه: باداجيس إسرائيل وكالات م.ض. شارع ريكيت 1، شوهف. المنتج: ميكا فارما، سپاير، ألمانيا.

تمّ التفتيح في تموز 2023 وفقاً لتعليمات وزارة الصحة.

رقم تسجيل الدواء في سجل الأدوية الرسمي في وزارة الصحة: 13839.31668 للتبسيط وتسهيل القراءة ورد نص هذه النشرة بصيغة المذكور. ومع ذلك، فالدواء مخصص لكلا الجنسين.

11.07.23

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) 1986

This medicine can be sold without a doctor's prescription

Swiss Relief® Spray Gel Solution

Active ingredient: 1 gram contains: Diclofenac Sodium 40 mg (4% w/w). Inactive ingredients and allergens in the medicine - see section 2 "Important information about some of the ingredients of this medicine" and section 6 "Additional information" in the leaflet.

Read this entire leaflet carefully before using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist.

You should use the medicine according to the instructions in section 3 of this leaflet. Consult the pharmacist if you need additional information. Contact the doctor if the symptoms of illness get worse or if they do not improve after 3 days.

1. What is the medicine intended for?

For local relief of mild to moderate pain and inflammation, following trauma of small to medium-sized joints and periarticular structures. Therapeutic group: Non-steroidal anti-inflammatory drugs (NSAIDs).

2. Before using the medicine

Do not use the medicine:

- If you are hypersensitive (allergic) to the active ingredient diclofenac sodium, to soy, to peanuts or to any of the other ingredients this medicine contains (see list in section 6).
- If you have ever had an allergic reaction to aspirin (acetylsalicylic acid) or to any other drug belonging to the non-steroidal anti-inflammatory class (NSAIDs) such as ibuprofen, which is manifested by difficulty in breathing, skin rash and runny nose.
- If you are in the last three months of pregnancy – please read section 2 "Pregnancy, breastfeeding and fertility".
- On open injuries, inflammations or infections of the skin as well as on eczema or mucous membranes.
- This medicine is not intended for children and adolescents under 15 years of age. Under this age contact the doctor.

Special warnings regarding the use of the medicine

Before using Swiss Relief Spray Gel, tell the doctor if:

- You have or have had stomach ulcers, liver or kidney problems, a tendency for bleeding or inflammatory bowel disease.
- You have previously suffered from asthma or allergies.

Additional warnings

- Do not spray in the eyes, nose or mouth, on open wounds or infected skin areas. If you accidentally get some spray into your eyes, rinse them thoroughly with clear water and inform your doctor.
- Never swallow the medicine.
- Do not sunbathe or use sunlamps whilst using this medicine.
- Discontinue using the medicine if any skin rash develops.
- Do not cover the treated area with occlusive bandages or plasters (waterproof or non-breathable).
- Do not use near an open flame, lit cigarette or some devices (e.g. hairdryers).

The possibility of systemic side effects from use of the medicine cannot be excluded if the medicine is used on large areas of skin and over a prolonged period.

Side effects may be reduced by using the minimum effective dose for the shortest possible duration.

Drug interactions

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially if you are taking:

- Tablets, capsules or suppositories for pain including those containing diclofenac sodium, acetylsalicylic acid (aspirin) or any other non-steroidal anti-inflammatory agent, such as ibuprofen. The use of other non-steroidal anti-inflammatory drugs (NSAIDs) (including acetylsalicylic acid or ibuprofen) at the same time with Swiss Relief Spray Gel may increase the risk of side effects.

Pregnancy, breastfeeding and fertility

Consult your doctor or pharmacist before taking any medicine. If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult your doctor before using Swiss Relief Spray Gel.

Do not use Swiss Relief Spray Gel during the last three months of pregnancy, as it could harm your unborn child or cause problems at delivery.

This product has a possible side effect of kidney damage to the fetus and reduced amniotic fluid,

from the 20th week of pregnancy. It is recommended to avoid using products from the NSAIDs group from the 20th week of pregnancy and to consult a medical staff member if necessary.

Swiss Relief Spray Gel should only be used under medical supervision during the first six months of pregnancy and the dose should be kept as low and duration of treatment as short as possible.

Swiss Relief Spray Gel should only be used under medical supervision during breastfeeding as diclofenac sodium passes into breast milk in small amounts. Additionally, Swiss Relief Spray Gel should not be applied on the breasts of nursing mothers nor elsewhere on large areas of skin or for a prolonged period of time.

Driving and using machines

Cutaneous application of Swiss Relief Spray Gel has no influence on the ability to drive or use machines.

Important information about some of the ingredients of this medicine This medicine contains:

- propylene glycol, which may cause mild localized skin irritation in some people. The medicine contains 30 mg propylene glycol in each pump stroke which is equivalent to 150 mg for each gram of solution.
- peppermint oil which may cause allergic reactions.
- soy, if you are allergic to peanuts or soy, do not use this medicine.
- 33.3 mg of alcohol (ethanol) per gram, which is equivalent to 3.3% w/w. It may cause a burning sensation on damaged skin.

3. How should you use the medicine?

Always use exactly as described in this leaflet or according to the doctor's or pharmacist's instructions. You should check with the doctor or pharmacist if you are not sure about the dosage and the treatment regimen of the medicine.

Swiss Relief Spray Gel is a spray containing a solution. The solution turns into a gel when sprayed onto the skin.

This medicine is not intended for infants and children under 15 years of age. Under this age refer to the doctor.

How to use

- Remove the protective cap.
- Hold the bottle in an upright position and use as directed on the painful or swollen site.
- Apply the recommended number of sprays.

The usual recommended dosage is: Adults and children aged 15 and over: 4 to 5 sprays applied 3 times a day. The number of sprays depends on the size of affected area. The maximum number of sprays is 15 times a day. The maximum single dose should not exceed 5 sprays.

Do not exceed the recommended dose

- The gel should be massaged gently into the skin. Wash your hands afterwards unless the treatment is intended for the hand.
- Wait until the gel has dried before covering the skin with clothes or bandage. Take care as the spray can stain your clothes if wet.
- Discontinue treatment when your symptoms (pain and swelling) improve.

Do not use for more than seven days without consulting your doctor.

- If there is no improvement in your symptoms after three days, or if your symptoms worsen, contact a doctor.

Avoid contact with the eyes or mucosal tissues.

Do not swallow the medicine! The medicine is intended for external use only.

If you have accidentally taken a higher dosage

If you have used a larger amount of your medicine than you should, wipe the excess Swiss Relief Spray Gel off with a tissue. If you or a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

If you forget to take the medicine at the designated time, use the spray as soon as you remember, but do not apply more than the recommended dose at once. Then carry on as before.

Do not use a double dose to make up for the forgotten dose.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions on the use of this medicine, consult the doctor or pharmacist.

4. Side effects

As with any medicine, use of Swiss Relief Spray Gel may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Stop using the medicine:

- If any skin rash develops. Following the use of topical (applied to the skin) medicines that contain diclofenac, reactions at the site of application have been reported commonly (in 1-10 out of 100 users). These reactions include rashes, itching, reddening, burning sensations or scaling of the skin.

STOP using the medicine and refer to a doctor immediately if you notice:

- Any of the following signs of allergy:
- Skin rash with blisters; (rare - may appear in 1-10 out of 10,000 users); hypersensitivity (including hives) (very rare - may appear in less than one out of 10,000 users).
- Wheezing, shortness of breath or feeling of tightness in the chest (asthma) (very rare - may appear in less than one out of 10,000 users).
- Swelling of the face, lips, tongue or throat (very rare - may appear in less than one out of 10,000 users).

Additional side effects:

Common side effects- effects that appear in 1-10 out of 100 users Skin rash, eczema, reddening of the skin, dermatitis (including contact dermatitis). Itching*.

Very rare side effects- effects that appear in less than one out of 10,000 users

- The skin may be more sensitive to the sun. Possible signs are sunburn with itching, swelling and blistering.
- Rash pustular.

Side effects with unknown frequency (effects for which a frequency has not yet been determined)

- Application site reactions, dry skin, burning sensation.

* Itching has been reported at a frequency of 0.9% in a clinical trial, 236 patients with ankle distortions were treated with 4-5 sprays of Swiss Relief Spray Gel 3 times a day (120 patients) or placebo (116 patients) for 14 days.

If the medicine is used for a prolonged period and/or it is used on large areas of the skin, systemic side effects such as: stomach pain and digestive system disorders, heartburn, liver or kidney problems and hypersensitivity reactions, may occur.

If a side effect appears, if one side effect gets worse or if you suffer from a side effect which is not mentioned in this leaflet, consult the doctor.

Reporting of side effects:

Side effects can be reported to the Ministry of Health by clicking on the link "Report adverse effects and problems associated with medications" that can be found on the home page of the Ministry of Health website (www.health.gov.il) directing to the online form of adverse events reporting or by clicking on the following link: <https://sideeffects.health.gov.il>. Additionally, side effects can be reported to Padagis via the following address: Padagis.co.il.

5. How to store the medicine?

- Avoid poisoning! This medicine and all other medicine should be kept in a close place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the bottle and package. The expiry date refers to the last day of that month.
- Store in the original package below 25°C.
- Can be used for 6 months after first opening, but not later than the expiry date.
- Do not dispose of the medicine via wastewater or household waste. Ask the pharmacist how to dispose of the medicine. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient the medicine also contains:

Purified water, Propylene glycol, Isopropylene alcohol, Soy bean lecithin 76%, Ethanol (anhydrous), Disodium phosphate dodecahydrate, Peppermint oil, Sodium dihydrogen phosphate dihydrate, Disodium edetate, Ascorbyl palmitate, Hydrochloric acid, Sodium hydroxide

What the medicine looks like and contents of the package:

Dark brown glass bottle with a spray nozzle. Contains a golden-yellow, transparent solution, which turns to a gel-like consistency after administration. Available in package size of 25 g.

Registration holder: Padagis Israel Agencies Ltd., 1 Rakefet St., Shoham. Manufacturer: Mika Pharma, Speyer, Germany.

Revised in July 2023 according to MOH guidelines.

Drug registration number at the National Drug Registry of the Ministry of Health: 13839.31668

11.07.23

Swiss Relief Spray Gel PIL PB0823-04