**Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986**
This medicine is to be supplied by physician's prescription only

# Swiss Relief Dual Release

## Capsules

Each capsule contains diclofenac sodium 75 mg.
Inactive ingredients and allergens: see section 6 "Additional information".

**Read the entire leaflet carefully before you start using this medicine.** This leaflet contains essential information about this medicine. If you have any further questions, refer to the physician or the pharmacist.
This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.
Swiss relief dual release is not suitable for children and adolescents under 18 years because the content of active substance is too high.

## 1. What is the medicine intended for?

Swiss Relief Dual Release is for the treatment of pain and inflammation due to: acute attack of gout, severe disorders of the musculoskeletal system, dental surgery or other minor surgery, joint function disturbances, lower back pain and cases of trauma (sprains, strains, fractures).

Because the release of the active substance diclofenac is modified, Swiss Relief Dual Release is not suitable for starting treatment in conditions where rapid onset of action is needed.

**Therapeutic group:** Non-steroidal anti-inflammatory drugs (NSAIDs).

## 2. Before using the medicine

**Do not use the medicine if:**
- You are sensitive (allergic) to the active ingredient diclofenac sodium or to any of the other ingredients that the medicine contains (see section 6 in the leaflet);
- If you are sensitive (allergic) to ibuprofen, aspirin or other medicines of the non-steroidal anti-inflammatory agents (NSAIDs) class;
- You have previously suffered from asthma exacerbations, swelling of the nasal mucosa or skin reactions after taking acetylsalicylic acid; or other NSAIDs;
- You suffer from unexplained haematopoietic disorders;
- You suffer from, or have a history of, peptic ulceration or gastric and duodenal haemorrhage (at least 2 different episodes of proven ulceration or bleeding);
- You have a history of gastrointestinal bleeding or perforation, associated with previous NSAID treatment;
- You suffer from cerebrovascular or other active bleeding;
- You suffer from severe hepatic failure or renal impairment;
- You suffer from severe cardiac impairment;
- You suffer from established heart disease and/or cerebrovascular disease e.g. if you have had a heart attack, stroke, mini-stroke (TIA) or blockages to blood vessels leading to the heart or brain or you have undergone an operation to clear or bypass blockages;
- You have or have had problems with your blood circulation (peripheral arterial disease);
- You are in the last trimester of pregnancy.

**Before treatment with Swiss Relief Dual Release, tell your physician if:**
- You smoke.
- You suffer from diabetes.
- You suffer from angina pectoris, blood clots, hypertension, a high level of cholesterol or triglycerides in the blood.

**Special warnings regarding the use of this medicine:**
- If there is no improvement in your condition within one month, consult the physician.
- Tell your physician if you are about to undergo laboratory tests, since treatment with this medicine may interfere with the results.
- Swiss Relief Dual Release may cause hypersensitivity during sun exposure; therefore, avoid exposure to the sun and take appropriate precautions (long clothes, a hat, protective creams, etc.).
- Side effects may be avoided by using the lowest effective dose for the shortest duration necessary for improvement of symptoms.
- Gastrointestinal safety:
  Avoid taking Swiss Relief Dual Release concomitantly with other NSAIDs, including COX-2 inhibitors (cyclo-oxygenase-2).
- Elderly patients:
  Elderly patients suffer from side effects more often following NSAID therapy, especially from effects like gastrointestinal bleeding and perforation, which may be life threatening in certain circumstances. Therefore, elderly patients should be monitored with particular care.
- Gastrointestinal bleeding, ulcers and perforations
  Gastrointestinal bleeding, ulcers or perforations, sometimes fatal, have been reported when using all NSAIDs. They have occurred with and without previous warning symptoms or any history of serious gastrointestinal events, and at any point in the treatment.
  The risk of gastrointestinal bleeding, ulceration or perforation is greater the higher the dose of the NSAID, in patients with a history of ulcers, especially with complications involving bleeding or perforation (see above "Do not use the medicine if"), and in elderly patients. These patients should start the treatment at the lowest available dose.
  For these patients, as well as for patients who need concomitant treatment with low dose acetylsalicylic acid (ASA) or other medicinal products, which can increase the gastrointestinal risk, a combination treatment with medicines, which protect stomach mucosa (e.g. misoprostol or proton pump inhibitors) should be considered.
  If you have a history of gastrointestinal side effects, particularly if you are elderly, you should report any unusual abdominal symptoms (especially gastrointestinal bleeding), especially at the beginning of treatment.
  Caution is advised if you are concomitantly taking medicines which can increase the risk of ulcers or bleeding, such as: oral corticosteroids; anticoagulants like warfarin; selective serotonin reuptake inhibitors, which are used, among other things, to treat depressive moods; or platelet aggregation inhibitors like aspirin (see below "Drug interactions").
  If gastrointestinal bleeding or ulcers occur while you are taking Swiss Relief Dual Release, treatment should be discontinued.
  Caution should be exercised when administering NSAIDs to patients with a history of gastrointestinal disease (ulcerative colitis, Crohn's disease), as their condition can worsen (see section 4 "Side effects").
- Effects on the cardiovascular system:
  Medicines like Swiss Relief Dual Release are associated with a slight increased risk of heart attacks (myocardial infarction) or strokes. The risk is more likely to be related to high doses of the medicines for prolonged treatment periods. Do not exceed the recommended dose or duration of treatment.
  If you have heart problems or have previously had a stroke or think that you might be at risk of these conditions (for instance, if you suffer from high blood pressure, diabetes or high cholesterol levels, or if you are a smoker) you should consult your physician. The dose must not exceed 100 mg per day, if you are being treated for more than four weeks.
  It is usually important to use the lowest dose for the minimal possible period of time, in order to keep the risk to develop cardiovascular side effects as low as possible. If, at any time while taking Swiss Relief Dual Release, you experience any signs or symptoms of heart or vascular problems such as chest pain, shortness of breath, weakness or slurred speech, contact your physician immediately.
- Skin reactions:
  Severe skin reactions accompanied by redness and blistering, sometimes fatal (exfoliative dermatitis - skin inflammation with significant skin peeling, Stevens-Johnson syndrome and toxic epidermal necrolysis/Lyell's syndrome: see section 4) have been reported rarely during NSAID treatment. It seems that the highest risk of such reactions occurs at the beginning of treatment, as in most cases these reactions occurred in the first month of treatment. Treatment with Swiss Relief Dual Release should be discontinued with the first signs of skin rashes, lesions of mucous membranes or other signs of a hypersensitivity reaction, and the physician should be consulted immediately.
- Hepatic effects:
  Caution must be exercised (discussion with the physician or pharmacist) prior to starting treatment in patients, who suffer from hepatic dysfunction, since their condition could worsen under treatment with diclofenac. When a prolonged or recurrent treatment is given with Swiss Relief Dual Release, regular monitoring of liver function is an appropriate precaution. Upon discovery of clinical signs of liver disease, treatment with Swiss Relief Dual Release should be discontinued immediately.
- Swiss Relief Dual Release should be given only after carefully evaluating the risk/benefit ratio in:
  - Certain congenital haematopoietic disorders (disorders of blood product production) (such as acute intermittent porphyria);
  - Certain autoimmune diseases (such as systemic lupus erythematosus and mixed connective tissue disorders).
- Special strict medical supervision is required:
  - Directly after major surgery;
  - In patients with allergies (such as skin reactions to other medicines, asthma, hay fever), chronic swelling of nasal mucous membranes or chronic respiratory disease, associated with obstruction of airways;
  - In patients with impaired kidney or liver function.
- Severe acute hypersensitivity reactions (such as anaphylactic shock) were observed in very rare cases. As first signs of a hypersensitivity reaction appear after taking Swiss Relief Dual Release, treatment must be stopped. Medically necessary procedures appropriate to the symptoms must be initiated by suitable specialists.
- Diclofenac might temporarily inhibit platelet aggregation. Therefore, patients suffering from coagulation disorders should be under strict observation.
- As with other NSAIDs, diclofenac can mask the signs and symptoms of an infection. In case signs of infection (such as redness, swelling, local heat, pain and fever) appear or worsen while taking Swiss Relief Dual Release, the physician should be consulted without delay.
- If you are taking Swiss Relief Dual Release before a surgical procedure, you should ask or tell the physician or dentist about it.
- During long-term use of analgesics, headaches might occur. They should not be treated with increased doses of the medicine. Consult your physician if you suffer from frequent headaches despite taking Swiss Relief Dual Release
- Generally, regular use of analgesics, especially when a combined therapy is given with several analgesic products, might lead to permanent kidney damage associated with a risk of kidney failure (analgesic nephropathy – renal impairment due to use of analgesics).
- As with other medicines, inhibiting prostaglandin synthesis, Swiss Relief Dual Release may cause difficulty becoming pregnant. You should inform your physician if you plan to become pregnant or if you suffer from difficulty becoming pregnant.

### Drug interactions

**If you are taking or have recently taken other medicines, including nonprescription medications and food supplements, inform your physician or pharmacist.** In particular inform your physician if you are taking:
- Digoxin - to strengthen the heart.
- Phenytoin - to treat convulsions.
- Lithium - to treat mental/emotional disorders. Taking Swiss Relief Dual Release concomitantly with these medicines might raise concentration of these medicines in the blood. Monitoring serum lithium levels is necessary. Monitoring serum levels of digoxin and phenytoin is recommended.
- Diuretics
- Medicines to treat high blood pressure and heart diseases - ACE inhibitors and angiotensin II antagonists. Swiss Relief Dual Release might decrease the effect of these medicines. Additionally, taking these medicines concomitantly, might increase the risk of impaired kidney function.
- Potassium sparing diuretics.
  Concomitant administration of Swiss Relief Dual Release with potassium sparing diuretics, might increase the concentration of potassium in the blood. Therefore, potassium blood level monitoring is recommended.
- Aspirin, salicylates and platelet aggregation inhibitors.
- Other medicines of NSAID class for treatment of pain and inflammation.
- Glucocorticosteroids.
- Antidepressants (selective serotonin reuptake inhibitors/ SSRIs).
  Concomitant administration of Swiss Relief Dual Release with these medicines increases the risk of gastrointestinal ulcers or bleeding.
- Methotrexate – for treatment of some types of cancer and arthritis. Giving Swiss Relief Dual Release less than 24 hours before or after the administration of methotrexate might raise the concentration of methotrexate in the blood and worsen its undesirable effects.
- Cyclosporine or tacrolimus - medicines for suppressing the immune system and sometimes used to treat rheumatism. NSAIDs (like diclofenac) might worsen the damaging effects of these medicines on the kidneys.
- Medicines which contain probenecid or sulfinpyrazone (medicines to treat gout) - might inhibit excretion of diclofenac. This might cause diclofenac to accumulate in the body and worsen its undesirable effects.
- Blood thinning medicines like warfarin - NSAIDs might increase the effect of these medicines.

**Using the medicine and food**
If you suffer from a sensitive stomach, the recommendation is to take Swiss Relief Dual Release during meals. Take with plenty of fluid.

**Using the medicine and alcohol consumption**
Do not drink alcoholic beverages while using the medicine.

**Pregnancy and breastfeeding**
Do not use the medicine without consulting the physician prior to beginning treatment if you are pregnant, planning to become pregnant or breastfeeding.

Pregnancy:
If you are found to be pregnant while taking Swiss Relief Dual Release, tell the physician. In the first and second trimester of pregnancy, Swiss Relief Dual Release should be taken only after discussion with the physician. Swiss Relief Dual Release should not be used in the last trimester of pregnancy, due to increased risk of complications for the mother and the baby.

Breastfeeding:
Small amounts of the active substance diclofenac and its breakdown products pass into breast milk. As no harmful effects on the baby are yet known, it is usually not necessary to stop breastfeeding during short term use. However, if long-term use or high doses are necessary, early weaning from breastfeeding should be considered.

**Driving and using machines**
As the use of Swiss Relief Dual Release, especially at higher-dosages, might cause central nervous system side effects such as tiredness and dizziness, reaction time can change in isolated cases, impairing the ability to drive and use machines. This is especially true while concomitantly consuming alcohol. You may not be able to react quickly or purposefully enough to unexpected or sudden events. In this case, you should not drive a car or other vehicles. Do not use tools or machinery. Do not work without reliable safety conditions.

**Smoking**
If you are a smoker – consult the physician (see above "Before treatment with Swiss Relief Dual Release, tell your physician if:").

## 3. How should you use the medicine?

Always use according to the physician's instructions. You must check with the physician or the pharmacist if you are uncertain about the dosage and treatment regimen of the medicine. The dosage and treatment regimen will be determined by the physician only.

To treat rheumatic diseases:
The dosage of diclofenac depends on the severity of the condition. The recommended dose range for adults lies between 50 and 150 mg diclofenac sodium per day.

| Age | Single dose:<br><br>Number of Swiss Relief Dual Release modified-release capsules | Total daily dose:<br><br>Number of Swiss Relief Dual Release modified-release capsules |
|---|---|---|
| Adults | 1<br>(equivalent to 75 mg diclofenac sodium) | 2<br>(equivalent to 150 mg diclofenac sodium) |

**Do not exceed the recommended dosage.**

Method of administration:
Modified-release capsules, hard for oral use.
Do not chew! Do not break the capsule.
The medicine should be swallowed with plenty of water.

Treatment duration:
The physician will determine the duration of treatment.
For Rheumatic Diseases, it may be necessary to take Swiss Relief Dual Release for a long time.
Please speak to your physician or pharmacist if you are under the impression that the effect of Swiss Relief Dual Release is too strong or too weak.

**Tests and follow-up**
During prolonged treatment with the medicine, or when treatment involves high dosages, the physician will regularly refer you to perform blood, urine and liver and kidney function tests.
Liver function values should be regularly monitored during long-term treatment.
If you are concomitantly taking blood thinning medicines to inhibit blood clotting or medicines to reduce blood sugar levels, coagulation function or blood sugar values should be monitored as a precaution.

**If you have accidently taken a higher dose**
Symptoms of overdose can be expressed as central nervous system disorders such as headache, dizziness, drowsiness and loss of consciousness (in children, also myoclonic seizures), and abdominal pain, nausea and vomiting. Furthermore, gastrointestinal bleeding and liver and kidney dysfunction are possible. A drop in blood pressure, slower/shallower breathing (respiratory depression) and blue-red discoloration of the skin and mucous membranes (cyanosis) may occur.

No specific antidote exists.

**If an overdose is suspected**, or if a child or someone else has accidentally swallowed the medicine, please inform your physician immediately, he or she can decide what are the necessary measures, depending on the severity of the toxic effects, or proceed to a hospital emergency room and bring the package of the medicine with you.

**If you forget to take the medicine** at the scheduled time, do not take a double dose. Take the next dose at the usual time and consult the physician.
Persist with the treatment as recommended by the physician.

**Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.**
**If you have questions regarding the use of the medicine, consult the physician or the pharmacist.**

## 4. Side effects

Like all medicines, Swiss Relief Dual Release may cause side effects in some users. Do not be alarmed while reading the list of side effects. You might not suffer from any of them. It must be borne in mind that the following side effects are predominantly dose related and differ from one patient to another. The most commonly observed side effects are effects on the gastrointestinal system. Peptic ulcers, perforations or haemorrhage in the stomach and in the duodenum, may develop and can be sometimes fatal, especially in elderly patients (see section "Special warnings regarding the use of this medicine"). Nausea, vomiting, diarrhoea, melena (black stool) constipation, indigestion, abdominal pain, heartburn, "tarry stool," vomiting blood, ulcerating inflammation of the mucous membrane of the mouth (ulcerative stomatitis), worsening of colitis and Crohn's disease (see section "Special warnings regarding the use of this medicine") have been reported after use. In less common cases, inflammation of the stomach lining has been observed. Fluid retention (oedema), hypertension and cardiac insufficiency have been reported in association with NSAID treatment.

There is a possible connection between Swiss Relief Dual Release use and a slight rise in the risk of heart attacks (myocardial infarction) or strokes.

- **Cardiac disorders:**
  Uncommon: palpitations, fluid retention (oedema), myocardial infarction (cardiac impairment), heart attack (sudden compressing chest pain), shortness of breath, difficulty breathing when lying down, swelling of the feet or legs (signs of cardiac insufficiency).
  These effects are manifested mainly with a high daily dose (150 mg) for a long period of time.
- **Blood and lymphatic system disorders:**
  Very rare: haematopoietic disorders (anaemia, leukopenia, thrombocytopenia, pancytopenia, agranulocytosis).
  The first signs might be: fever, sore throat, superficial lesions in the mouth, flu like symptoms, severe exhaustion, nosebleeds and subcutaneous bleeding.
  **Stop using the medicine and refer to the physician immediately if any of these side effects occur.**
  Do not self-treat with any medicines to reduce pain or fever.
  In very rare cases: haemolytic anaemia (anaemia caused by accelerated breakdown of red blood cells) might develop.
- **Nervous system disorders:**
  Common: central nervous system disorders such as headaches, dizziness, drowsiness, agitation, irritability or fatigue.
  Very rare: impaired sensitivity, impaired sense of taste, impaired memory, confusion, convulsions, tremor.
- **Eye disorders:**
  Very rare: visual impairment (blurred vision and diplopia).
- **Ear disorders:**
  Very rare: noise in the ear (tinnitus), temporary hearing impairment.
- **Gastrointestinal disorders:**
  Very common: gastrointestinal disorders such as nausea, vomiting and diarrhoea, and also slight gastrointestinal blood loss, which can cause anaemia in exceptional cases.
  Common: ingestion disorders (dyspepsia), flatulence, abdominal cramps, loss of appetite and gastrointestinal ulcers (in some circumstances with bleeding and perforation).
  Uncommon: vomiting blood, blood in the stool, tarry stools or bloody diarrhoea.
  **If you suffer from quite severe pain in the upper abdomen, tarry stool or blood in the stool, you should stop using the medicine and refer to a physician immediately.**
  Very rare: inflammation of the mucous membranes of the mouth, inflammation of the tongue, lesions of the oesophagus, constipation and lower abdominal disorders, such as inflammation and bleeding of the large intestine, worsening of Crohn's disease/ulcerative colitis (specific inflammations of the large intestine associated with ulceration), inflammation of the pancreas (pancreatitis). Narrowing of the intestine has been reported in very rare cases.
- **Renal and urinary disorders:**
  Uncommon: development of oedema (retention of fluid in the body), especially in patients suffering from high blood pressure or impaired kidney function.
  Very rare: damage to renal tissue (interstitial nephritis, papillary necrosis), which can be accompanied by acute renal failure, protein in the urine (proteinuria) and/or blood in the urine (haematuria); Nephrotic syndrome (fluid retention in the body [oedema] and excessive protein excretion in the urine). Reduced urine excretion, fluid retention in the body (oedema), and malaise (a general feeling of illness) might be manifestations of kidney disease or even kidney failure.
  **If any of these effects occur or worsen, you should stop using the medicine and refer to your physician immediately.**
- **Skin and subcutaneous tissue disorders:**
  Uncommon: hair loss.
  Very rare: skin rash accompanied by redness (eczema, erythema, exanthema), hypersensitivity to light (ensure skin protection), small spots of subcutaneous bleeding, severe skin reactions like skin rash accompanied by blisters (such as Stevens-Johnson syndrome, toxic epidermal necrolysis/ Lyell's syndrome).
- **Infections:**
  In very rare cases, worsening of inflammations due to infection (e.g. development of a necrotic condition in the subcutaneous tissues - necrotizing fasciitis) has been described in the time span of administration of specific anti-inflammatory medicines (NSAIDs, the group to which Swiss Relief Dual Release belongs).

  **If signs of an infection appear or worsen (such as redness, swelling, local heat, pain and fever) while using Swiss Relief Dual Release, refer to the physician immediately.**

  In very rare cases, symptoms of non-infectious meningitis (aseptic meningitis), such as severe headache, nausea, vomiting, fever, spinal pain, neck stiffness and muscle stiffness or clouding of consciousness and loss of orientation ability have been observed. It seems that the risk is greater for patients who are already suffering from certain autoimmune diseases (systemic lupus erythematosus, connective tissue disorders).
- **Vascular disorders:**
  Very rare: high blood pressure (hypertension).
- **Immune system disorders:**
  Common: hypersensitivity reactions such as skin rash and itching of the skin.
  Uncommon: nettle rash (urticaria).
  Very rare: **severe general hypersensitivity reactions. These reactions may be expressed as swelling of the face, tongue and pharynx, lips and extremities, with constriction of airways, shortness of breath, tachycardia, drop in blood pressure, up to the point of anaphylactic shock. If one of these symptoms develops, which might occur even during the first use, seek medical attention immediately. Additionally, stop using Swiss Relief Dual Release and refer to the physician immediately.**
  In very rare cases, allergic inflammation of the blood vessels (vasculitis) and the lungs (pneumonia) have been observed.
- **Hepatobiliary disorders:**
  Common: raised levels of liver enzymes in the blood.
  Uncommon: liver damage, especially during long-term treatment, acute hepatitis with or without jaundice [very rarely, with a very severe (fulminant) course, even without early signs].
- **Psychiatric disorders:**
  Very rare: psychotic reactions, depression, a feeling of anxiety, nightmares.

**If a side effect appears, if one of the side effects worsens, or when you suffer from a side effect not mentioned in the leaflet, you should consult the physician.**

**Reporting Side Effects:**
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage website (www.health.gov.il), which directs to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il
Additionally, you can report to Perrigo via the following address: www.perrigo-pharma.co.il.

## 5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the physician.
- Do not use the medicine after the expiry date (exp. date) that appears on the package and blister. The expiry date refers to the last day of that month.
- Even if kept in their original container and stored as recommended, medicines may be kept for a limited period only. Please note the expiry date of the product! In case of doubt, you should consult the pharmacist who dispensed the medicine to you.
- Store below 25°C.
- Store in the original package.

## 6. Additional information

**In addition to the active ingredient the medicine also contains:**
Microcrystalline cellulose, gelatin, povidone K 25 ,methacrylic acid ethyl acrylate copolymer (1:1) neutralized with sodium hydroxide, talc, ammonio methacrylate copolymer type B, colloidal anhydrous silica, propylene glycol, ammonio methacrylate copolymer type A, titanium dioxide, triethylcitrate, indigo carmine ,sodium lauryl sulphate, printing ink.

**What does the medicine look like and contents of the package:**
Hard gelatin capsules, with a white "D75M" imprinting on the capsule cap and body. Colour of the capsule cap: opaque light blue, colour of the capsule body: transparent.
Packs size of 4, 10, 20 and 56 capsules packed in blisters.
Not all pack sizes may be marketed.

**Registration holder and address:**
Perrigo Israel Agencies Ltd., 1 Rakefet St., Shoham.

**Manufacturer and address:**
Swiss Caps GmbH, Bad Aibling, Germany.

This leaflet was checked and approved by the Ministry of Health in: July 2015.

**Registration number of the medicine in the National Drug Registry of the Ministry of Health:** 14210.31815

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