PATIENT PACKAGE INSERT
IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986
The medicine is dispensed with a doctor's prescription only

Swiss Relief Dual Release

Capsules, 75 mg

Active ingredient:
Each capsule contains:
Diclofenac sodium 75 mg
[25 mg diclofenac sodium in gastro-resistant (quick-release) + 50 mg diclofenac sodium in prolonged-release form].
Inactive and allergenic ingredients in the preparation: see section 6 "Further information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine.
If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Swiss Relief Dual Release is a non-steroidal anti-inflammatory drug (NSAID) and analgesic used for the treatment of symptoms of: rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, acute musculoskeletal disorders, such as periarthritis, tendinitis, tenosynovitis, bursitis, sprains, strains and dislocation, relief of fracture-related pain, lower back pain, acute gout, psoriatic arthropathy.
For treatment of pain and inflammation associated with orthopedic, dental and minor surgeries.
Since release of the active ingredient diclofenac is prolonged, Swiss Relief Dual Release is not suitable for treatment of conditions in which a rapid effect of the medicine 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 additional ingredients contained in the medicine (see section 6 "Further information" in the leaflet).
- you now have or have ever had a recurring stomach (gastric) or duodenal (peptic) ulcer or intestinal bleeding (at least 2 different proven events of ulcers or bleeding).
- you suffered in the past from an allergic reaction to acetylsalicylic acid (aspirin) or other NSAIDs. The reaction can include asthma, swelling of the nasal mucous membrane or skin reactions.
- you have an unexplained blood disorder.
- you have ever suffered from bleeding or gastrointestinal perforation related to previous NSAID therapy.
- you are suffering from bleeding in the brain (cerebrovascular bleeding) or other active bleeding.
- you are suffering from a severe liver or kidney disease.
- you have been diagnosed with a heart disease and/or cerebrovascular disease, for example, if you have had a heart attack, stroke or mini-stroke (transitory ischemic attack [TIA]), or if you are suffering from blockages in blood vessels leading to the heart or brain or underwent an operation to open or bypass such blockages.
- you are suffering, or have suffered in the past, from blood circulation problems (peripheral arterial disease).
- you are suffering from severe heart failure.
- you are in the last trimester of pregnancy

The medicine is not intended for use in children and adolescents under 18 years of age since the active ingredient content in it is too high.

Special warnings regarding use of the medicine
Before treatment with Swiss Relief Dual Release, tell the doctor if you:
- smoke.
- have diabetes.
- have angina pectoris, blood clots, high blood pressure, high blood level of cholesterol or triglycerides.
- are due to undergo or recently had surgery on the stomach or intestine before taking Swiss Relief Dual Release, since the medicine may sometimes delay intestinal wound healing after surgery.
- think you may be sensitive (allergic) to diclofenac sodium, aspirin, ibuprofen or other NSAIDs, or to any of the additional ingredients in Swiss Relief Dual Release (listed at the end of this leaflet). Signs of an allergic reaction include swelling of the face and mouth (angioedema), difficulty breathing, chest pain, runny nose, skin rash or any other allergic reaction.

Safety in the gastrointestinal tract:
Avoid taking Swiss Relief Dual Release together with other NSAIDs, including COX-2 (cyclo-oxygenase-2) inhibitors.
Side effects can be reduced by taking the lowest effective dosage for the shortest duration necessary to alleviate the symptoms.
Elderly patients:
In elderly patients, the side effects are more common after taking NSAIDs, particularly bleeding and perforations in the stomach and intestine, which may be life-threatening. Therefore, close monitoring by the doctor during the course of treatment is required for elderly patients.
Gastrointestinal bleeding, ulcers and perforations:
Gastrointestinal bleeding, ulcers and perforation, which can be fatal, have been reported with use of all NSAIDs. They can occur at any time during treatment, with or without prior warning symptoms or a history of serious gastrointestinal events. In patients with a history of ulcers, particularly if complicated with bleeding or perforation (see section 2 "Do not use the medicine if") and/or elderly patients, the risk of gastrointestinal bleeding, ulcers and perforations is higher with increasing NSAID dosage. In these cases, patients should start treatment at the lowest possible dosage.
For these patients, and in cases in which the treatment includes a low dosage of acetylsalicylic acid (aspirin) or other medicines that may increase the risk of undesirable gastrointestinal effects, the doctor should consider combination treatment with medicines that protect the stomach lining (e.g., misoprostol or proton pump inhibitors).
If you have a history of gastrointestinal side effects, particularly if you are elderly, report all unusual stomach symptoms (especially gastrointestinal bleeding), particularly at the start of treatment.
Caution is recommended if you are concomitantly taking medicines that could increase the risk of ulcers or bleeding, such as oral corticosteroids, blood thinners such as warfarin, selective serotonin reuptake inhibitors (SSRIs) or antiplatelet medicines, such as aspirin (see in section 2 "Drug interactions").
In case of gastrointestinal bleeding or ulcer, stop taking Swiss Relief Dual Release.
Patients with a history of gastrointestinal disease (ulcerative colitis, Crohn's disease) should exercise caution when taking NSAIDs as their condition may worsen (see section 4 "Side effects").
Effects on the heart and blood vessels:
Taking medicines such as Swiss Relief Dual Release may be associated with a small increased risk of heart attack or stroke. It is likely that the risk is higher with high dosages and prolonged treatment. Do not exceed the recommended dosage or the recommended treatment duration.
If you have heart problems, or have had a stroke or think that you might be at risk of these conditions (for example, if you have high blood pressure, diabetes, high cholesterol levels or if you are a smoker), consult the doctor about the treatment.
Since the cardiovascular risks may increase with the increased dose and duration of treatment, use the lowest effective dosage for the shortest duration of time.
Skin reactions:
Serious skin reactions, some of them fatal (exfoliative dermatitis – a skin inflammation with substantial skin peeling, Stevens-Johnson syndrome and toxic epidermal necrolysis/Lyell syndrome) have been reported in very rare cases during treatment with NSAIDs (see section 4 "Side effects"). The highest risk for these reactions appears to be at the start of treatment, with the reactions occurring within the first month in the majority of cases. Stop taking Swiss Relief Dual Release and consult a doctor immediately at the first signs of a skin rash, mucosal lesions or any other signs of hypersensitivity.
Effects on the liver:
If the patient suffers from liver problems, speak to the doctor before starting treatment, as treatment with diclofenac may cause them to worsen. When prolonged or recurring treatment with Swiss Relief Dual Release is given, the doctor will regularly monitor liver function as a precautionary measure. If clinical signs consistent with liver disease develop, stop treatment with Swiss Relief Dual Release immediately.
Additional information:
Only use Swiss Relief Dual Release after carefully weighing the risk/benefit ratio in the following cases:
- a congenital blood disorder (such as acute intermittent porphyria).
- systemic lupus erythematosus, mixed connective tissue disease or a similar condition.

Close medical surveillance is required:
- ○ immediately after major surgery.
- ○ in patients with allergies (for example, skin reactions to other medicines, asthma, hay fever), chronic swelling of the nasal mucous membrane or a chronic respiratory disease that narrows the airway.
- ○ in patients with kidney or liver problems.

Severe acute hypersensitivity reactions (such as anaphylactic shock) have been reported very rarely. Stop taking Swiss Relief Dual Release at the first sign of a hypersensitivity reaction and take the necessary steps to alleviate symptoms.
Diclofenac can temporarily reduce the blood's ability to clot. Therefore, patients suffering from blood-clotting disorders must be closely monitored by the doctor.
As with other NSAIDs, diclofenac can mask the signs and symptoms of infection. If you notice signs of an infection (such as redness, swelling, feeling hot, pain and high fever) or worsening of an existing infection while taking Swiss Relief Dual Release, refer to a doctor immediately.
If you are taking medicines to prevent clotting or to lower blood sugar levels, the doctor will regularly monitor the blood levels as a precaution.
During prolonged use of Swiss Relief Dual Release, the doctor will monitor kidney function and test the blood levels regularly.
If you are taking Swiss Relief Dual Release before surgery, tell the doctor or dentist.
Prolonged use of pain relievers can cause headaches. Do not treat headaches with high dosages of the medicine. Talk to your doctor if you are experiencing frequent headaches while taking Swiss Relief Dual Release.
In general, habitual use of pain relievers, especially when using multiple pain relievers at the same time, may cause permanent kidney damage and even kidney failure (analgesic nephropathy).
As with other medicines that inhibit prostaglandin synthesis, Swiss Relief Dual Release may make it difficult for you to get pregnant. Tell your doctor if you plan to become pregnant or if you are having difficulties getting pregnant.

Children and adolescents
For use in children and adolescents, see in section 2 "Do not use the medicine if".

Drug interactions
If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular, inform the doctor or pharmacist if you are taking:
- digoxin (to strengthen the heart), phenytoin (to treat seizures) or lithium (to treat mental illnesses). Taking Swiss Relief Dual Release together with these medicines can increase the concentration of these medicines in the blood. Your doctor will monitor the blood lithium levels. Your doctor will likely monitor the blood digoxin and phenytoin levels.
- diuretics and antihypertensives. Swiss Relief Dual Release can decrease the effect of these medicines.
- ACE inhibitors and angiotensin receptor blockers (to treat congestive heart failure and high blood pressure). Swiss Relief Dual Release can decrease the effect of these medicines. Taking these medicines at the same time can also increase the risk of kidney problems.
- potassium-sparing diuretics. Taking Swiss Relief Dual Release together with potassium-sparing diuretics can increase the blood potassium concentration. In this case, your doctor will monitor the blood potassium levels.
- other NSAIDs or corticosteroids. Taking Swiss Relief Dual Release with these medicines increases the risk of gastrointestinal ulcers or bleeding.
- antiplatelet medicines such as acetylsalicylic acid (aspirin) and certain antidepressants (SSRIs). Taking Swiss Relief Dual Release with these medicines can increase the risk of gastrointestinal bleeding.
- methotrexate. Taking Swiss Relief Dual Release less than 24 hours before or after taking methotrexate can increase the concentration of methotrexate in the blood and worsen its undesirable effects.
- ciclosporin (to prevent organ transplant rejection and to treat rheumatic diseases). NSAIDS such as diclofenac worsen the harmful effect of ciclosporin on the kidneys.
- medicines containing probenecid or sulfinpyrazone (medicines to treat gout). These medicines can prolong the time diclofenac remains in the body. This can lead to an accumulation of diclofenac in the body and worsen its undesirable effects.
- blood thinners such as warfarin. NSAIDs can increase the effect of these medicines.

Use of the medicine and food
If you have a sensitive stomach, it is recommended that Swiss Relief Dual Release be taken with food. Take the medicine with a large amount of fluids.

Use of the medicine and alcohol consumption
Do not drink alcoholic beverages during the course of treatment with the medicine.

Pregnancy, breastfeeding and fertility
If you are pregnant, plan to become pregnant, or are breastfeeding, do not use the medicine without consulting a doctor before starting treatment.
Pregnancy:
If you discover that you are pregnant while taking Swiss Relief Dual Release, tell the doctor. Swiss Relief Dual Release can only be taken in the first and second trimesters of pregnancy after consulting with the doctor. Do not take Swiss Relief Dual Release in the last trimester of pregnancy due to the increased risk for the mother and baby.
This preparation has a potential side effect of kidney damage to the unborn baby and reduced amniotic fluid starting from week 20 of pregnancy. It is recommended to avoid using NSAIDs starting from week 20 of pregnancy, and to consult with a healthcare professional, if needed.
Breastfeeding:
Small amounts of the active ingredient diclofenac and its metabolites pass into breast milk. Since no detrimental effects on infants are known to date, it is usually not necessary to stop breastfeeding with short-term use. However, consider early weaning if your doctor prescribed the medicine for prolonged use or at high dosages to treat an inflammation.
Fertility:
Inform the doctor if you are planning to become pregnant or if you are having difficulties becoming pregnant (see in section 2 "Before treatment with Swiss Relief Dual Release, tell the doctor if you:").

Driving and operating machinery
As the use of Swiss Relief Dual Release, particularly at higher dosages, can cause side effects in the central nervous system, such as fatigue and dizziness, reaction time may be affected in isolated cases, while impairing the ability to drive and use machinery, especially when taken in combination with alcohol. You may be unable to react to unexpected or sudden events in time. If you notice this, do not drive, operate machinery or engage in any other potentially hazardous activity.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain regarding the dosage and treatment regimen of the medicine. The dosage and treatment regimen will be determined by the doctor only. The usual dosage is generally:
To treat rheumatic disease:
The dosage of Swiss Relief Dual Release is based on the severity of the disease. The range of recommended dosages for adults ranges from 50 to 150 mg diclofenac sodium per day.

Age	Single Dose: Number of Swiss Relief Dual Release Capsules	Maximum Daily Dose: Number of Swiss Relief Dual Release Capsules
Adults	1 (equivalent to 75 mg diclofenac sodium)	2 (equivalent to 150 mg diclofenac sodium)

Do not exceed the recommended dose.
Duration of treatment:
The doctor will determine the duration of treatment.
For rheumatic diseases, prolonged use of Swiss Relief Dual Release may be necessary.
Talk to the doctor or pharmacist if you feel that the effect of Swiss Relief Dual Release is too strong or too weak.
Method of administration:
Hard capsules for oral use.
Do not chew! Do not break the capsule. Swallow the capsule whole with a lot of water.

Tests and follow-up
During the course of prolonged treatment with the medicine or treatment that requires high dosages, the doctor will routinely refer you for blood, urine, and liver and kidney function tests.
Monitor liver function values regularly during the course of long-term treatment.
If you are concomitantly taking blood thinners to prevent blood coagulation or medicines to lower the blood sugar level, monitor coagulation functions or blood sugar values as a precautionary measure.

If you accidentally took a higher dosage
Overdose can cause central nervous system symptoms, such as headache, dizziness, drowsiness and loss of consciousness (including myoclonic seizures in children) as well as stomach pain, nausea and vomiting. It may also cause gastrointestinal bleeding, liver and kidney problems, decreased blood pressure, decreased breathing (respiratory depression) and a bluish discoloration of the skin and mucous membranes (cyanosis).
There is no specific antidote.
In case of suspicion of an overdose or if a child or someone else has accidentally swallowed the medicine, please inform the doctor immediately. He/she can decide on the necessary measures, depending on the severity of the poisoning, or, alternatively, proceed immediately 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 a doctor.
Adhere to the treatment regimen as recommended by the doctor.
Do not take medicines in the dark! Check the label and dose each time you take a medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Swiss Relief Dual Release 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.
Side effects are ranked under the following categories:
Very common: More than 1 in 10 users
Common: 1-10 in 100 users
Uncommon: 1-10 in 1,000 users
Rare: 1-10 in 10,000 users
Very rare: Fewer than 1 in 10,000 users
Unknown: Frequency cannot be estimated from the available data
Some of the side effects may be serious.
Stop using the medicine and consult a doctor immediately if one of the following side effects occurs:
Mild cramping and tenderness of the stomach starting shortly after the start of the treatment with Swiss Relief Dual Release and followed by rectal bleeding or bloody diarrhea, usually within 24 hours of the onset of stomach pain (frequency unknown and cannot be estimated from the available data).
Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.

Possible side effects:
The side effects listed below are largely dependent on the dosage and vary from person to person.
The most commonly reported side effects are in the digestive tract. Stomach and duodenal ulcers (peptic ulcers), perforations or bleeding, sometimes fatal, may develop, especially in elderly patients (see in section 2 "Special warnings regarding use of the medicine"). Nausea, vomiting, diarrhea, flatulence, constipation, indigestion, stomach pain, black stool, vomiting blood, ulcers in the mouth (ulcerative stomatitis), worsening of ulcerative colitis or Crohn's disease (see in section 2 "Special warnings regarding use of the medicine") have been reported after use. Inflammation of the stomach lining is less common.
Swelling (edema), high blood pressure and heart failure have been reported in association with NSAID treatment.
There is a possible connection between medicines such as Swiss Relief Dual Release and a slightly increased risk of heart attack or stroke.
Heart:
Very rare: fast/irregular heartbeat (palpitations), edema, heart failure, heart attack.
Blood and lymphatic system:
Very rare: blood system disorders (anemia, leukopenia, thrombocytopenia, pancytopenia, agranulocytosis).
The first signs may be: fever, sore throat, mouth ulcers, flu-like symptoms, extreme tiredness, nosebleeds and bruising.
If one of these side effects occurs, stop taking the medicine and refer to a doctor immediately.
Do not treat these symptoms yourself with any pain relievers or fever reducers. The doctor will regularly monitor your blood counts during long-term treatment.
Very rare: hemolytic anemia (low red blood cell count due to red blood cells being destroyed faster than they are produced).
Nervous system:
Common: central nervous system disturbances such as headache, dizziness, drowsiness, agitation, irritability, tiredness.
Very rare: tingling/numbness sensation in the fingers, taste changes, impaired memory, disorientation, spasms, shaking.
Eyes:
Very rare: vision disturbances (blurry or double vision).
Ears:
Very rare: noises in the ear (tinnitus), temporary hearing impairment.
Gastrointestinal tract:
Very common: gastrointestinal symptoms such as nausea, vomiting and diarrhea, as well as mild gastrointestinal blood loss that may result in low red blood cell count (anemia) in rare cases.
Common: indigestion (dyspepsia), flatulence, stomach pain, loss of appetite, gastrointestinal ulcers (sometimes with bleeding and perforation).
Uncommon: vomiting blood (hematemesis), bloody stool, black stool or bloody diarrhea.
If you experience moderate or severe upper stomach pain, you vomited blood, or if your stool is black or bloody, stop using the medicine and refer to a doctor immediately.
Very rare: inflammation and sores in the mouth, inflammation of the tongue, problems with the esophagus (esophageal lesions), constipation and lower stomach problems, such as inflammation and bleeding in the large intestine, worsening of Crohn's disease/ulcerative colitis (certain types of inflammation of the large intestine accompanied by ulcers), inflammation of the pancreas (pancreatitis), narrowing of the intestine.
Kidneys and urinary system:
Uncommon: edema, particularly in patients with high blood pressure or kidney problems.
Very rare: kidney tissue damage (interstitial nephritis, papillary necrosis) accompanied by acute kidney failure, protein in the urine (proteinuria) and/or blood in the urine (hematuria), nephrotic syndrome (edema and a very high amount of protein in the urine).
Reduced urination, edema and malaise can be signs of kidney disease or even kidney failure.
If one or more of these symptoms occurs or worsens, stop taking the medicine and refer to a doctor immediately.
Skin and subcutaneous tissue:
Uncommon: hair loss.
Very rare: red skin rash (eczema, erythema, exanthema), sensitivity to light, bruising, severe skin reactions, such as skin rash with blisters (for example, Stevens-Johnson syndrome, toxic epidermal necrolysis/Lyell syndrome).
Infections and parasitic diseases:
Very rare: worsening of inflammation caused by an infection (such as an invasive infection in the soft tissues that causes necrosis – necrotizing fasciitis) in conjunction with the use of NSAIDs, including Swiss Relief Dual Release.
If you notice signs of an infection (such as redness, swelling, feeling hot, pain and fever) or worsening of an existing infection while taking Swiss Relief Dual Release, refer to a doctor immediately.
Very rare: symptoms of noninfectious meningitis (aseptic meningitis) such as migraine, nausea, vomiting, fever, stiff neck or drowsiness. People with certain autoimmune diseases (systemic lupus erythematosus, a mixed connective tissue disease) appear to be at greater risk.
Blood vessels:
Very rare: high blood pressure (hypertension).
Immune system:
Common: hypersensitivity reactions, such as rash and itchiness.
Uncommon: hives (urticaria).
Very rare: severe hypersensitivity (allergy) reactions. These reactions may manifest as swelling of the face, tongue and voice box, with a narrowing of the airways, shortness of breath, fast heartbeat, drop in blood pressure or life-threatening shock.
If one of these symptoms occurs (symptoms may occur during first use), immediately seek medical assistance. In addition, if you notice any of these symptoms, stop taking the medicine immediately and refer to a doctor.
Very rare: inflammation of the blood vessels (vasculitis) and lungs (pneumonitis) caused by an allergic reaction.
Liver and gallbladder:
Common: high liver enzyme levels in the blood.
Uncommon: liver damage, particularly with long-term treatment, acute hepatitis, possibly with jaundice (very rarely severe [fulminant], even without early warning signs).
Therefore, the doctor will regularly monitor liver function during the course of long-term treatment.
Psychiatric disorders:
Very rare: psychotic reactions, depression, anxiety, nightmares.
Follow the instructions above for certain side effects.
If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.
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 (www.health.gov.il), that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il
In addition, you can report to Padagis via the following address: Padagis.co.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe 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 package and blister. The expiry date refers to the last day of that month.
- Do not discard medicines in the household waste (e.g., toilet or sink). Ask the pharmacist where to dispose of medicines that are no longer in use. These measures will help protect the environment.
- Store below 25°C.
- Store in the original package.

6. FURTHER 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 (E 171), triethylcitrate, indigo carmine (E 132), sodium lauryl sulfate, printing ink.
What the medicine looks like and the contents of the package:
Hard gelatin capsules, with "D75M" printed in white on the cap and body of the capsule. Capsule cap color: opaque light blue, capsule body color: transparent.
Swiss Relief Dual Release comes in packages of the following sizes: 4, 10, 20, 56 capsules packaged in blisters.
Not all package sizes may be marketed.
Registration holder and address:
Padagis Israel Agencies Ltd., 1 Rakefet St., Shoham.
Manufacturer and address:
Swiss Caps GmbH, Bad Aibling, Germany.
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14210.31815

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