

Patient package insert according to Pharmacists' Regulations (Preparations) –1886

This medicine can be sold with a physician's prescription only

Betaren® 100 SR, Slow Release Tablets

Each tablet contains Diclofenac Sodium 100 mg

Inactive ingredients and allergens in the medicine - see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of this medicine".

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.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if you think that their medical condition is the same as yours.

1. What is the medicine intended for?

To treat rheumatoid arthritis, osteoarthritis, low back pain and other acute musculoskeletal disorders such as periarthritis, tendonitis, tenosynovitis, bursitis, sprains, strains and dislocation, ankylosing spondylitis and acute gout. For control of pain and inflammation in orthopedic, dental and other minor surgery.

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

NSAIDs are intended for relief of pain and inflammation

2. Before using the medicine

Do not use the medicine if:

- You are hypersensitive (allergic) to the active ingredient (diclofenac sodium), aspirin, ibuprofen or to any other non-steroidal anti-inflammatory drugs (NSAIDs) or to any of the other ingredients this medicine contains (see section 6). Signs of a hypersensitivity reaction include swelling of the face and mouth (angioedema), breathing problems, chest pain, runny nose, skin rash or any other allergic type reaction.
- You have now, or have ever had (twice or more) a stomach (gastric) or duodenal (peptic) ulcer, or bleeding in the digestive tract (this can include blood in vomit, bleeding when emptying bowels, blood in stool or black stool).
- You have had stomach or bowel problems after you have taken other NSAIDs.
- You have heart, kidney or liver failure.
- You have heart disease and/or cerebrovascular disease, e.g.: if you have had a heart attack, stroke, mini-stroke (TIA) or blockages to blood vessels to the heart or brain or catheterization or bypass surgery.
- You have or have had problems with your blood circulation (peripheral arterial disease).
- You are more than six months pregnant.

Special warnings regarding the use of the medicine

Before the treatment with Betaren, tell the doctor if:

- You suffer from any stomach or bowel disorders including ulcerative colitis or Crohn's disease.
- You have kidney or liver problems, or you are elderly.
- You have a condition called porphyria.
- You suffer from any blood or bleeding disorder. If you do, your doctor may ask you to go for regular check-ups while using the medicine.
- You ever had asthma, seasonal allergic rhinitis, swelling of the nasal mucosa (nasal polyps), chronic pulmonary diseases or infections of the respiratory tract.

- You are breastfeeding
- You have angina, blood clots, high blood pressure, raised cholesterol or raised triglycerides.
- You have heart problems or if you had a stroke or if you think you might be at risk of these conditions (for example, if you have high blood pressure, diabetes or high cholesterol or if you are a smoker)
- You have diabetes
- You smoke
- You have Systemic Lupus Erythematosus SLE (inflammatory, auto-immune disorder which causes symptoms such as joint pain, joint inflammation, skin rashes, fever) or any similar condition.

Tell your doctor if you recently had or you are going to have a surgery of the stomach or intestinal tract before taking **Betaren**, as **Betaren** can sometimes worsen wound healing in your intestines after surgery.

Consult your doctor if one or more of the conditions above apply to you, because Betaren might not be suitable for you.

Other special warnings

- You should take the lowest effective dose of diclofenac sodium for the shortest possible time particularly if you are underweight or elderly.
- There is a small increased risk of heart attack or stroke when you are taking any medicine like diclofenac sodium. The risk is higher if you are taking high doses for a long time. Always follow the doctor's instructions on the dosage and how long to take the medicine for.
- If at any time while taking **Betaren** you experience any signs or symptoms of problems with your heart or blood vessels such as chest pain, shortness of breath, weakness or slurring of speech, refer to a doctor immediately.
- Whilst you are taking medicines of this type, your doctor may ask you to have periodic check-ups.
- If you have a history of stomach problems when you are taking NSAIDs, particularly if you are elderly, you must tell your doctor immediately if you notice any unusual symptoms.
- Because it is an anti-inflammatory medicine, diclofenac sodium tablets may reduce the symptoms of infection, for example, headache, and high temperature. If you feel unwell and need to see a doctor, remember to tell him or her that you are taking diclofenac sodium tablets.
- There may be an increase in liver enzymes which requires discontinuation of treatment after consulting your doctor, so for prolonged treatment with the medicine liver functions tests should be performed (see section 4 "Side Effects").

Children

Betaren is not intended for use in children

Drug interactions

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Some medicines can interfere with your treatment. Tell your doctor or pharmacist, especially if you are taking:

- Medicines to treat diabetes
- Anticoagulants (for blood thinning e.g., warfarin)
- Diuretics (water tablets)
- Lithium (used to treat certain mental problems)
- Methotrexate (for treatment of certain inflammatory

diseases and certain types of cancer)

- Ciclosporin, tacrolimus (to treat certain inflammatory diseases and after transplants)
- Trimethoprim (a medicine used to prevent or treat urinary tract infections)
- Quinolone antibiotics (to treat infections)
- Any other NSAIDs or COX-2 (cyclo-oxygenase-2) inhibitors, for example aspirin or ibuprofen
- Mifepristone (a medicine used to terminate pregnancy)
- Cardiac glycosides (for example digoxin), used to treat heart problems
- Medicines of the SSRIs (selective serotonin re-uptake inhibitors) group (to treat depression)
- Oral steroids (anti-inflammatory)
- Medicines used to treat heart conditions or high blood pressure, for example beta blockers or angiotensin converting enzyme (ACE) inhibitors
- Voriconazole (a medicine used to treat fungal infections)
- Phenytoin (a medicine used to treat seizures)
- Colestipol/cholestyramine (used to lower cholesterol)

Use of this medicine and food

Take this medicine with or after food

Pregnancy, breastfeeding and fertility

Although not common, abnormalities have been reported in babies whose mothers have taken NSAIDs during pregnancy. You should not take **Betaren** if you are in the last three months of pregnancy, as it may affect the baby's blood circulation.

- You should consult your doctor or pharmacist if you think you might be pregnant or if you are in the first 6 months of pregnancy.
- Taking **Betaren** may make it more difficult for you to become pregnant. Consult your doctor if you are planning to become pregnant, or if you have problems getting pregnant.
- You should avoid taking **Betaren** whilst breastfeeding.

Driving and using machines

Very occasionally people have reported that diclofenac sodium tablets have made them feel dizzy, tired or sleepy. Problems with eyesight have also been reported. If you are affected in this way, you should not drive or operate machinery.

Important information about some of the ingredients of this medicine

Betaren contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains less than 1 millimole (23mg) sodium per tablet, meaning that in effect it is "sodium free".

3. How to use this medicine

Always use this medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.

The dosage and manner of treatment will be determined by the doctor only. The usual recommended dosage is: one tablet per day. The medicine is not suitable for children.

Do not exceed the recommended dose.

Swallow the tablet whole with a glass of water, with or after food. Do not crush/halve/chew the tablets as these are slow-release tablets.

The doctor may instruct you to take **Betaren** at the same time as another medicine to protect the stomach, particularly if you have had stomach problems before, or if you are elderly, or taking certain other medicines as well.

If you have accidentally taken a higher dosage

Symptoms of an overdose can include: headache, nausea (feeling sick), vomiting, abdominal pain, stomach or intestinal bleeding, diarrhoea (rarely), disorientation, excitation, coma, drowsiness, dizziness, ringing in the ears, fainting, or occasionally convulsions (seizures, uncontrolled fits).

If you have taken an overdose or if 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 forgot to take the medicine

It is very important that you do not miss a dose. If you forgot to take this medicine at the designated time, take a dose as soon as you remember. If it is nearly time for your next dose, just take the next dose and forget about the one you missed.

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

If you have trouble remembering to take the tablets, tell your doctor or pharmacist.

Continue with the treatment as recommended by the doctor.

Even if there is an improvement in your health, do not stop taking this medicine without consulting the doctor.

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

Like any medicine, the use of **Betaren** 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.

Some side effects may be serious

Stop taking this medicine and refer to the doctor immediately with the appearance of:

- Sudden and crushing chest pain (signs of myocardial infarction or heart attack)
- Breathlessness, difficulty breathing when lying down, swelling of the legs or feet (signs of heart failure)
- Sudden weakness or numbness in the face, arm or leg especially on one side of the body; sudden loss or disturbance of vision; sudden difficulty in speaking or ability to understand speech; sudden migraine-like headaches which happen for the first time, with or without disturbed vision. These symptoms can be an early sign of a stroke
- Stomach pain, indigestion, heartburn, wind, nausea or vomiting
- Any sign of bleeding in the stomach or intestine, for example, when emptying your bowels, blood in vomit or black, tarry stool
- Allergic reactions which can include skin rash, itching, bruising, painful red areas, peeling or blistering
- Wheezing or shortness of breath (bronchospasm)
- Swollen face, lips, hands or fingers
- Signs of liver function disturbances (rise in liver enzymes – see section "special warnings regarding use of this medicine") including liver failure or signs of liver inflammation such as: rash or itching, stomach pain or tenderness, diarrhoea, dark urine, nausea, fatigue, flu-like symptoms or jaundice (yellowing of your skin or the whites of your eyes)
- Persistent sore throat or high temperature
- An unexpected change in the amount of urine produced and/or its appearance.
- Mild cramping and tenderness of the abdomen, starting shortly after the start of the treatment with

Betaren and followed by rectal bleeding or bloody diarrhoea usually within 24 hours of the onset of abdominal pain

• Stevens-Johnson syndrome (serious illnesses with blistering of the skin, mouth, eyes and genitals)

If you notice that you are bruising more easily than usual or have frequent sore throats or infections, **tell your doctor.**

Tell your doctor immediately if you notice the following:

- Chest pain, which can be a sign of a serious allergic reaction called Kounis syndrome

Additional side effects

Common side effects (effects that appear in 1-10 out of 100 users):

- Stomach pain, heartburn, nausea, vomiting, diarrhoea, indigestion, wind, loss of appetite
- Headache, dizziness, vertigo
- Skin rash or spots
- Raised levels of liver enzymes in the blood

Uncommon side effects (effects that appear in 1-10 out of 1,000 users):

- Fast or irregular heart beat (palpitations), chest pain, heart disorders, including heart attack or breathlessness, difficulty breathing when lying down, or swelling of the feet or legs (signs of heart failure), especially if you have been taking a higher dose (150 mg per day) for a long period of time.

Rare side effects (effects that appear in 1-10 out of 10,000 users):

- Stomach ulcers or bleeding (there have been very rare reported cases resulting in death, particularly in the elderly)
- Gastritis (inflammation, irritation or swelling of the stomach lining)
- Vomiting blood
- Diarrhoea with blood in it or bleeding from the rectum
- Black, tarry stool
- Drowsiness, tiredness
- Skin rash and itching
- Edema (fluid retention), symptoms of which include swollen ankles
- Liver function disorders, including hepatitis (liver inflammation) and jaundice
- Asthma (symptoms may include wheezing, breathlessness, coughing and a tightness across the chest)

Very rare side effects (effects that appear in less than 1 in 10,000 users):

Effects on the nervous system:

Inflammation of the lining of the brain (meningitis), tingling or numbness in the fingers, tremor, visual disturbances such as blurred or double vision, taste changes, hearing loss or impairment, tinnitus (ringing in the ears), sleeplessness, nightmares, mood changes, depression, anxiety, irritability, mental disorders, disorientation, loss of memory, fits, headaches together with a dislike of bright lights, fever and a stiff neck.

Effects on the stomach and digestive system:

Constipation, inflammation of the tongue, mouth ulcers, inflammation of the inside of the mouth or lips, lower gut disorders (including inflammation of the colon or worsening of ulcerative colitis or Crohn's disease).

Effects on the chest or blood:

Hypertension, hypotension (symptoms may include faintness, giddiness), inflammation of blood vessels (vasculitis), pneumonitis, blood disorders (including anaemia).

Effects on the liver or kidneys:

Kidney or severe liver disorders including liver failure, presence of blood or protein in the urine.

Effects on the skin or hair:

Facial swelling, serious skin rashes including Stevens-Johnson syndrome, toxic epidermal necrolysis and other skin rashes which may get worse by exposure to sunlight, hair loss.

Effects on the reproductive system:

Impotence.

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

Throat disorders, confusion, hallucinations, malaise (general feeling of discomfort), inflammation of the nerves in the eye, disturbances of sensation.

Medicines such as diclofenac may be associated with a small increased risk of heart attack or stroke.

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

Side effects can be reported to the Ministry of Health via the link

"דיווח על תופעות לוואי עקב טיפול תרופתי" 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 via the following link: <https://sideeffects.health.gov.il>

5. How to store the medicine

• Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants 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 (התאריך) stated on the package. The expiry date refers to the last day of that month.

• **Storage conditions:** Store below 25°C

• Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:

Compressible sugar, cetostearyl alcohol, talc, povidone, silica colloidal anhydrous, hypromellose, magnesium stearate, titanium dioxide (E171), sucrose, macrogol 400, copovidone, gum acacia, carnauba wax, iron oxide red (E172).

What the medicine looks like and what the package contains:

Pink, round tablet, biconvex, debossed with "D1CL100" on one side.

Approved package sizes are: 10, 20, 30 tablets. Not all package sizes may be marketed.

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Drug registration number at the national drug registry of the Ministry of Health: 015-73-24619-00

Betaren SR 100 PIL PB0321-05

Manufacturer and registration holder:

Dexcel® Ltd.

1 Dexcel St., Or Akiva 3060000, Israel