PACKAGE LEAFLET: INFORMATION FOR THE USER

Diclofenac sodium Sandoz® injection 75 mg/3 ml, solution for injection 25 mg/ml
Diclofenac Sodium

Read all of this package leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this package leaflet. You may need it again later.
- Do you have any further questions? If so, please contact your doctor or pharmacist.
- This medicine has been prescribed to you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- Are you experiencing any of the side effects listed in Section 4? Or do you have any side effects not mentioned in this package leaflet? If so, please contact your doctor or pharmacist.

Contents of this package leaflet

1. WHAT IS DICLOFENAC SODIUM SANDOZ INJECTION AND WHAT IS THIS MEDICINE USED FOR?

This medicine belongs to the drug group called non-steroidal anti-inflammatory drugs (NSAIDs). These medicines are used to treat pain and inflammation.
This medicine relieves the symptoms of inflammation, such as pain and swelling, and also reduces fever. It has no effect on the cause of the inflammation or the fever.
This medicine is administered by injection into the muscle (intramuscular).

This medicine is used for:
- acute, severe pain due to rheumatic-type inflammation of joints and/or wear and tear of joints (arthrosis), including certain back problems (inflammation of the vertebral joints)
- inflammation around shoulder or shoulder blade
- a sudden gout attack
- renal colic
- biliary colic
- painful inflammation and swelling after surgery

2. WHEN SHOULD YOU NOT USE THIS MEDICINE OR WHEN SHOULD YOU BE EXTRA CAREFUL WITH IT?

When should you not use this medicine?
- if you are allergic to one of the substances in this medicine. You can find a list of these substances in Section 6.
- you have or had a stomach or intestinal ulcer, or you have bleeding in the gastrointestinal tract. The symptoms of this are blood in the stool or a black, tarry stool.

- you have ever had stomach or bowel problems, such as bleeding or black stools, after taking painkillers with anti-inflammatory and antipyretic action (NSAIDs).
- during the last three months of pregnancy.
- if you have ever had an asthma attack, a skin rash with severe itching and formation of bumps (urticaria), a "hay fever-like" runny nose, or swelling of the face, lips, tongue, throat and/or limbs (symptoms of angioedema) after taking other NSAIDs such as acetylsalicylic acid or ibuprofen.
- in case of bleeding or bleeding disorders.
- in case of blood count abnormalities.
- in case of reduced production of blood cells in the bone marrow (bone marrow depression).
- if you have been diagnosed with a heart condition or cerebrovascular disorder; for example, you have had a heart attack, stroke, mini-stroke (TIA) or a blockage of the blood vessels to the heart or brain, or you have had surgery for this (for example, bypass surgery).
- if you have or have had problems with your blood circulation (peripheral arterial disease).
- if your liver is severely impaired or does not work.
- if your kidneys are severely impaired or do not work.

Please tell your doctor if you have recently had or will soon have surgery of the gastrointestinal tract before taking/using this medicine, as this medicine may sometimes impair wound healing in your intestines after surgery.

If any of the above warnings apply to you, or if you are unsure, contact your doctor or pharmacist.

When should you be extra careful with this medicine?
Talk to your doctor or pharmacist before using this medicine:
- if you think you might be allergic to Diclofenac sodium, aspirin, ibuprofen or another NSAID or to one of the other ingredients found in Diclofenac sodium Sandoz (these are listed at the end of the package leaflet). Signs of a hypersensitivity reaction include swelling of the face and mouth (angioedema), difficulty breathing, chest pain, runny nose, skin rash or other allergic reaction.
- if you have recently had or will soon have surgery of the gastrointestinal tract, as Diclofenac sodium Sandoz can sometimes impair wound healing in your intestines after surgery.
- if you smoke
- if you have diabetes (diabetes mellitus)
- if you have an oppressive, painful feeling in your chest (angina), blood clots, high blood pressure or an increased amount of cholesterol or triglycerides (certain fats) in your blood
- if you experience the first signs of skin rash, mucous membrane damage or any other sign of hypersensitivity
- if you suffer from gastrointestinal symptoms. Your doctor may ask you to come for regular check-ups while you are taking these tablets
- if you have ever experienced stomach problems while taking painkillers with anti-inflammatory and anti-fever effects (NSAIDs), especially if you are older than 65 years, you should contact your doctor immediately in case of unusual symptoms
- if you have recurrent, severe inflammation of any part of the intestines (Crohn's disease) or of the large intestine (ulcerative colitis)
- if you have asthma, hay fever, or other long-term respiratory problems such as nasal polyps, chronic obstructive pulmonary disease, or chronic respiratory infection
- if you have impaired liver or kidney function
- if you think you are dehydrated, e.g., from diarrhoea or illness or a major surgery

- if you have blood clotting disorders or other blood disorders, including rare liver disease, porphyria
- if you think you are dehydrated, e.g., from diarrhoea or illness or a major surgery
- if you have the inflammatory disease systemic lupus erythematosus or any other connective tissue disorder
- if you have chickenpox (varicella)

Medicines such as Diclofenac Sodium Sandoz injection may be associated with a minor increased risk of heart attack (myocardial infarction) or stroke. Do not take more than the prescribed dose, and do not take the medicine for longer than the prescribed treatment period. The risk of side effects can be reduced by using the lowest effective dose for the shortest possible time.

Monitoring during treatment with this medicine
If you have liver or renal impairment or abnormal blood counts, your blood will be tested during treatment. These tests will check liver function (transaminases level), kidney function (creatinine level) or blood count (number of white and red blood cells and platelets). Your doctor will decide whether the use of this medicine should be stopped or changed based on these tests.

Elderly (65 years and older)
Elderly patients may be more sensitive to the effects of this medicine than other adults, particularly frail elderly patients, or elderly people with low body weight.
If you are over 65 years of age, it is important to use the lowest possible dose that is still effective for your condition. Especially for elderly patients, it is important to report side effects immediately to their doctor.

Diclofenac may reduce or mask symptoms of infection such as headache or high body temperature. This may make it more difficult to detect or treat the infection. If you feel unwell and visit a doctor, do not forget to mention that you are taking this medicine.

Are you also taking other medicine?
Apart from Diclofenac Sodium Sandoz injection 75 mg/3 ml, do you use any other medicine, or have you used any recently or is there the possibility that you may use other medicines in the near future? Please inform your doctor or pharmacist. This also applies to non-prescription medicines.

Concomitant use of this medicine with the following medicines may increase the risk of bleeding or ulcers. You must tell your doctor if you are taking any of the following medicines:
- adrenal cortex hormones (corticosteroids), used to treat inflammation of body parts
- medicines that prevent the formation of blood clots (anticoagulants and platelet aggregation inhibitors)
- certain antidepressants, so-called selective serotonin reuptake inhibitors (SSRIs)
- other medicines used to treat pain, swelling and other symptoms of inflammation (NSAIDs), such as acetylsalicylic acid or ibuprofen. Bleeding from the gastrointestinal tract or the formation of ulcers can be side effects of all NSAIDs, including this medicine. This problem, which can be more severe in elderly people, can occur at any time during treatment with or without warning signs or a previous history of severe gastrointestinal problems.

You must also inform your doctor if you are taking any of the following medicines:
- lithium, an antidepressant
- digoxin, used in certain heart diseases
- amiodarone, used for irregular heartbeat
- certain medicines that suppress the natural defences (methotrexate, cyclosporine, and tacrolimus)
- blood-sugar-lowering medicines taken by mouth (oral antidiabetics)

- water pills (diuretics)
- antihypertensive medicines (antihypertensives, such as ACE inhibitors or beta-blockers)
- trimethoprim used to prevent or treat a urinary tract infection
- quinolones, a group of medicines for certain bacterial infections
- certain medicines used to treat high blood cholesterol levels (colestipol and cholestyramine)
- fluconazole and voriconazole, used to treat fungal infections
- sulfinpyrazone, used to treat gout
- phenytoin, used to treat seizures
- rifampicin, used to treat tuberculosis and leprosy, among others

Fertility, pregnancy, and lactation
Are you pregnant, do you think you are pregnant, do you want to become pregnant, or are you breastfeeding? Please contact your doctor or pharmacist before taking this medicine.

- Do not use this medicine during the first 6 months of the pregnancy unless recommended by your doctor.
- This medicine should not be used during the last 3 months of pregnancy, as it may be harmful to the unborn child or cause problems during delivery.
- As with other NSAIDs, this medicine may make it more difficult to become pregnant. If you plan to become pregnant or have previously had problems becoming pregnant, it is better not to use this medicine.
- Do not use this medicine if you are breastfeeding. This can be harmful to your baby.

Your doctor will discuss the potential risks of taking this medicine during pregnancy with you.

Driving and operating machinery
This medicine does not affect the ability to drive and operate machinery. However, do not drive or operate machinery if you experience any side effects such as dizziness, drowsiness, or blurred vision (see Section 4).

Diclofenac Sodium Sandoz injection contains benzyl alcohol
Benzyl alcohol should not be used in premature infants or new-borns. It can cause toxic reactions and allergic reactions in infants and children under 3 years of age.

Diclofenac Sodium Sandoz injection contains propylene glycol
This medicine contains 600 mg propylene glycol per ampoule. If your baby is less than 4 weeks old, contact your doctor or pharmacist before administering this medicine, particularly if your baby is also receiving other medicines containing propylene glycol or alcohol.

This medicine contains less than 1 mmol of sodium (23 mg) per ampoule, meaning it is essentially “sodium-free”.

3. HOW DO YOU TAKE THIS MEDICINE?

Always take this medicine exactly the way your doctor or pharmacist has told you. Do you have doubts about the correct usage? If so, please contact your doctor or pharmacist.

Your doctor will know how much of this medicine to administer.

The recommended dose may not be exceeded. It is important to use the lowest possible dosage for pain relief. In addition, this medicine should not be used for longer than necessary.

Use in adults
In adults, the contents of one ampoule per day are usually given over a period of two days. In some cases, the contents of two ampoules may be given. If continuation of use with Diclofenac Sodium Sandoz is necessary, this can be done in the form of, for example, Diclofenac tablets.

Use in the elderly (65 years and older)
Elderly patients appear to be at greater risk of potential side effects from NSAIDs. Therefore, it is important that the elderly are treated with the lowest possible dose that still has an effect.

Use in children
This medicine is not suitable for use in children.

Method of administration
The injection fluid is drawn from the ampoule into a syringe and injected deep into your gluteal muscle.

Duration of the treatment
Your doctor will tell you how long you should take Diclofenac Sodium Sandoz injection 75 mg/3 ml.
During long-term treatment, your doctor may want to monitor you regularly, even if you do not suffer from any of the above conditions (see "What is this medicine used for?").

Have you taken too much of this medicine?
Overdose may occur if more than the prescribed amount is used. Symptoms of an overdose may include vomiting, diarrhoea, dizziness, ringing in the ears (tinnitus), seizures/convulsions, severe stomach pain or bloody or black stools. If you think too much of this medicine has been administered, tell your doctor or nurse immediately.

Have you forgotten to take this medicine?
Since this medicine is administered by your doctor or nurse, it is unlikely that a dose will be missed. If you have any concerns about this, please contact your doctor or nurse.

Do you have any other questions about taking this medicine? If so, please contact your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some side effects can be severe.

Stop using this medicine and contact your doctor immediately if you notice one or more of the following side effects:
- Mild abdominal cramps and abdominal tenderness that occurred shortly after starting the treatment with this medicine and followed by rectal bleeding or bloody diarrhoea usually within 24 hours of the first occurrence of abdominal pain (frequency unknown, cannot be determined from available data).
- Chest pain, which may be a sign of a potentially severe allergic reaction called Kounis syndrome.

Side effects may include:

- very common (in more than 1 in 10 patients);
- common (in less than 1 in 10 patients);
- rare (in less than 1 in 100 patients);
- very rare (in less than 1 in 1,000 patients);
- extremely rare (in less than 1 in 10,000 patients);
- not known (cannot be determined with the available data).

Infections and parasitic infestations
Very rare: Local accumulation of pus at the injection site, caused by inflamed tissue.

Blood and lymphatic system disorders
Very rare: Blood platelet deficiency with symptoms of bruising and increased risk of bleeding (thrombocytopenia); white blood cell deficiency with increased susceptibility to infections (leukopenia); insufficient red blood cells in the blood (anaemia); severe blood disorder with much fewer white blood cells that can cause sudden high fever, severe sore throat, and mouth ulcers (agranulocytosis).

Immune system disorders
Rare: (Severe) hypersensitivity reactions (including low blood pressure and shock).
Very rare: Sudden swelling of the skin and mucous membranes (e.g., throat or tongue), causing difficulty in breathing and/or itching and skin rash, often as an allergic reaction (angioedema).

Psychiatric disorders
Very rare: Confusion (disorientation); (severe) despondency (depression); insomnia; nightmares, irritability; mental disorders involving delusions, hallucinations and/or confusion; anxiety.

Nervous system disorders
Common: Headache; dizziness.
Rare: Drowsiness.
Very rare: Perception of tickling, itching, or tingling without any cause (paraesthesia); memory disorder; attack of unconsciousness with muscle twitches (convulsions); trembling; stiff neck (a symptom of meningitis); taste disorders (dysgeusia); stroke caused by cerebral infarction or cerebral haemorrhage (cerebrovascular accident (CVA)).

Eye disorders
Very rare: Vision impairment; blurred vision; double vision.

Ear and labyrinth disorders
Common: Balance disorders accompanied by nausea (vertigo).
Very rare: Ringing in the ears; damaged hearing.

Heart and blood vessel disorders
Uncommon: Palpitations; chest pain; insufficient power to pump the heart (heart failure); heart attack.
Very rare: Increased blood pressure (hypertension); inflammation of a blood vessel (vasculitis).
Not known: Occurrence of chest pain and allergic reactions (signs of Kounis syndrome).

Respiratory diseases
Rare: Asthma (including shortness of breath).
Very rare: Benign inflammation of the lung tissue (pneumonitis).

Gastrointestinal disorders
Common: Nausea; vomiting; diarrhoea; gastrointestinal disturbances with symptoms of feeling full or having pain in the stomach area, burping, nausea, vomiting and/or acid reflux (dyspepsia); abdominal pain; flatulence; decreased appetite.
Rare: Inflammation of the stomach wall (gastritis); bleeding in the gastrointestinal tract; vomiting of blood; bloody diarrhoea, blood in the stool; gastrointestinal ulcer (with or without bleeding or the formation of a hole in the gastrointestinal wall).
Very rare: Inflammation of the large intestine (colitis) including recurrent, severe inflammation of the large intestine with ulceration (ulcerative colitis) or recurrent (severe) inflammation of part of the intestine (Crohn's disease); constipation (obstipation); inflammation of the oral mucosa (stomatitis); inflammation of the tongue (glossitis); abnormality of the oesophagus; narrowing of the intestine; inflammation of the pancreas, with symptoms of severe pain in the upper abdomen radiating to the back, nausea and vomiting (pancreatitis).

Hepatobiliary disorders
Common: Increase in certain enzyme levels.
Rare: Inflammation of the liver (hepatitis) (fatal in some cases); jaundice (yellow discolouration of the skin or the whites of the eyes).
Very rare: Liver abnormality, death of liver tissue (hepatic necrosis); liver failure.

Skin conditions
Common: Skin rash.
Rare: Skin rash with severe itching and the formation of bumps (urticaria).
Very rare: Blistering skin inflammation (dermatitis bullosa); eczema; redness of the skin (erythema); skin rash with irregular red spots (erythema multiforme); severe hypersensitivity reaction with high fever, blisters on the skin, joint pains and/or inflammation of the eye (Stevens-Johnson syndrome); severe, sudden allergic reaction with symptoms of fever and blisters on the skin and peeling of the skin (toxic epidermal necrolysis); severe skin inflammation with loss of epidermis and hair (exfoliative dermatitis); hair loss (alopecia); hypersensitivity to light or sunlight; bruising in the skin and mucous membranes; itching.

Bladder, urinary tract, and kidney disorders
Very rare: Sudden insufficient functioning of the kidneys (renal failure); blood in the urine; an excessive amount of protein in the urine (proteinuria); fever and pain in the flanks due to loss of renal function (nephrotic syndrome); inflammation of the kidneys accompanied by blood in the urine, fever, and pain in the flanks (tubulointerstitial nephritis); death of kidney tissue (renal papillary necrosis).

General conditions and administration site disorders
Common: Reaction at the injection site, pain at the injection site, hardening at the injection site
Rare: Fluid retention in tissue (oedema); death of tissue at the injection site.
Not known: Tissue damage at the injection site.

Most side effects occur in the gastrointestinal tract. Stomach ulcers, bleeding, or the formation of a hole in the gastrointestinal tract may occur and sometimes have a fatal outcome, especially in the elderly (see Section 2). Nausea, vomiting, diarrhoea, flatulence, constipation, digestive disorder, abdominal pain, blood in the stool, vomiting of blood, inflammation of the oral mucosa with ulceration, aggravation of colitis and Crohn's disease (chronic inflammation of the small and/or large intestine) (see Section 2) have been reported following administration. Inflammation of the stomach wall was observed less frequently.
Medicines such as Diclofenac Sandoz injection 75 mg/3 ml may be associated with a minor increased risk of heart attack (myocardial infarction) or stroke.

Reporting side effects
If you experience side effects, please consult your doctor or pharmacist. This also applies to possible side effects that are not listed in this package leaflet. You can also report side effects directly through the Netherlands Pharmacovigilance Centre, Lareb, www.lareb.nl. By reporting side effects, you can help us to gather more information about the safety of this medicine.

5. HOW DO YOU STORE THIS MEDICINE?

Store below 25°C. Store in the original packaging to protect against light.

Keep out of reach and sight of children.

Do not use this medicine after the expiry date. This is stated on the packaging after "EXP:". It shows a month and a year. The expiry date refers to the last day of that month.

Do not flush medicines down the sink or the toilet and do not throw them in the rubbish bin. Ask your pharmacist how to dispose of medicines you are no longer using. That way they will be destroyed in a responsible way and not end up in the environment.

6. CONTENTS OF THE PACKAGING AND OTHER INFORMATION

What substances are there in this medicine?
- The active substance in this medicine is Diclofenac Sodium.
- The other substances include benzyl alcohol, N-acetylcysteine, sodium hydroxide, mannitol, propylene glycol and water for injection.

What does Diclofenac Sodium Sandoz injection 75 mg/3 ml look like and how many are in a pack?

Pharmaceutical form and content
Solution for injection.
Every ampoule contains 75 mg Diclofenac Sodium per 3 ml.

Packaging size
1 or 5 glass ampoules in cardboard holders in a cardboard box.

Not all pack sizes may be marketed.

Marketing authorisation holder and manufacturers

Marketing authorisation holder
Sandoz B.V., Veluwezoom 22, 1327 AH Almere, The Netherlands

Manufacturer
LEK Pharmaceuticals, dated
Verovškova 57
1526 Ljubljana
Slovenia

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