

PACKAGE LEAFLET: INFORMATION FOR THE USER

DICLO-XL 100
[diclofenac sodium]

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Diclo-XL 100 are and what they are used for
2. What you need to know before you take Diclo-XL 100
3. How to take Diclo-XL 100
4. Possible side effects
5. How to store Diclo-XL 100
6. Contents of the pack and other information

1. What Diclo-XL 100 are and what they are used for

Diclo-XL 100 contains the active substance diclofenac sodium. Diclofenac sodium is one of the group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

Diclo-XL 100 may be used for the relief of pain and swelling in a wide range of chronic (long-term) (arthritis affecting the joints) conditions including arthritis (swelling of a joint), osteoarthritis and ankylosing spondylitis (arthritis affecting the spine and pelvis).

Diclo-XL 100 is specially formulated to release the active ingredient slowly, over a long period of time.

2. What you need to know before you take Diclo-XL 100
Do not take Diclo-XL 100 if:

- You are allergic to diclofenac sodium or any of the other ingredients of this medicine (listed in section 6)
- You think you may be allergic to diclofenac sodium, aspirin, ibuprofen or any other NSAID, or to any of the other ingredients of Diclo-XL 100, (These are listed at the end of the leaflet.) 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, a stomach (gastric) or duodenal (peptic) ulcer, or bleeding in the digestive tract (this can include blood in vomit, bleeding when emptying bowels, fresh blood in faeces or black, tarry faeces)
- You have had stomach or bowel problems after you have taken other NSAIDs
- You have severe heart, kidney or liver failure
- You have 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 to the heart or brain or 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.

If you suffer from any of the following at any time during your treatment **STOP TAKING** the medicine and seek immediate medical help:

- Pass blood in your faeces (stools/motions)
- Pass tarry black stools
- Vomit any blood or dark particles that look like coffee grounds.
- **STOP TAKING** the medicine and tell your doctor if you experience: indigestion or heartburn, abdominal pain (pains in your stomach) or other abnormal stomach symptoms.

Warnings and precautions

Tell your doctor if you recently had or you are going to have a surgery of the stomach or intestinal tract before receiving/ taking/using Diclo-XL 100, as Diclo-XL 100 can sometimes worsen wound healing in your gut after surgery

Talk to your doctor, pharmacist or nurse before taking Diclo-XL 100 if you:

- Suffer from asthma, or any other breathing condition
- Are an elderly person
- Have System Lupus Erythematosus (SLE or 'Lupus') or other connective tissue disorders

- Suffer from any stomach or bowel disorders including ulcerative colitis or Crohn's disease
- Have porphyria (enzyme deficiency affecting the chemicals responsible for blood production in the body)
- Suffer from any blood or bleeding disorders
- Are a female attempting to conceive
- Have kidney or liver problems.

Make sure your doctor knows, before you are given diclofenac:

- If you smoke
- If you have diabetes
- If you have angina, blood clots, high blood pressure, raised cholesterol or raised triglycerides.

Medicines such as Diclo-XL 100 may be associated with a small increased risk of heart attack (myocardial infarction) or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment.

Side effects may be minimised by using the lowest effective dose for the shortest duration necessary.

If you go into hospital to see a doctor or you have a dental appointment, tell them that you are taking Diclo-XL 100.

If you suffer from any blood or bleeding disorder your doctor may ask you to have regular check ups while taking these tablets.

Other medicines and Diclo-XL 100

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines.

Especially:

- Aspirin, ibuprofen or other non-steroidal anti inflammatory drugs for pain relief (e.g naproxen, diclofenac)
- Anticoagulants such as warfarin to prevent blood clots
- Antihypertensives to treat high blood pressure
- Methotrexate and ciclosporin used to treat rheumatoid arthritis and psoriasis
- Corticosteroids used as anti-inflammatory treatments
- Mifepristone (now or at any time in last 12 days)
- Lithium used in the treatment of depression
- Diuretics (water tablets) used to treat blood pressure and water retention
- Digoxin and other medicines used to treat heart problems
- Phenytoin used to treat epilepsy
- Sulphonylureas such as gliclazide or glibenclamide used to treat diabetes
- SSRIs (Selective serotonin reuptake inhibitors) used to treat depression such as fluoxetine and paroxetine
- Anti-platelet agents used to prevent blood clots from forming that can lead to heart attack or stroke e.g aspirin, clopidogrel, ticlopidine, dipyridamole
- Tacrolimus used for immunosuppression
- Zidovudine used in the treatment of AIDS and HIV infection
- Trimethoprim used to prevent or treat urinary tract infections
- Colestipol/cholestyramine used to lower cholesterol
- Voriconazole used to treat fungal infections
- Quinolone antibiotics used to treat infections.

Diclo-XL 100 with food and drink

Always take the tablets with plenty of water, preferably with a meal. Try to take them at the same times every day.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Diclofenac does pass into the mother's milk; therefore breast-feeding should be avoided if taking Diclo-XL 100.

Diclo-XL 100 should not be taken in the last 3 months of pregnancy.

Diclo-XL 100 may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

Driving and using machines

Undesirable effects such as visual disturbances, dizziness, vertigo, drowsiness and tiredness are possible after taking medicines of this type. If you are affected do not drive or operate machinery.

Diclo-XL 100 contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

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Front Page

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ARTWORK DETAIL LABEL

Product	DICLO-XL 100			
Buyer/Country	Strides Pharma UK Ltd.	Component	Pack Insert	
Dimension	180 x 280 mm	Pack	--	
New Item Code	1039999	Old Item Code	1018504	
Colour Shades	■ Black	No. of Colours	1	
Change Control No.	PC-ODF/2019/342 Record Number: 237403		Artwork Version	2.0
Design/Style	Front & Back Printing. To be supplied in the unfolded size.			
Substrate	60 GSM paper.			
Special Instructions	PRINTING CLARITY TO BE CLEAR AND SHARP.			
Autocartonator Requirements	Pack insert supply should be as per auto-cartonator. Refer auto-cartonator drawing for instructions.			
Caution to the printer: Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform PDC for further action. DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.				

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3. How to take Diclo-XL 100

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The lowest effective dose should be used for the shortest possible time.

Use in adults and the elderly:

The recommended dose is 100mg (one tablet) daily, taken whole with plenty of water preferably with food or after food.

Elderly patients are more likely to experience side effects. Therefore treatment should be started on the lowest possible dose for the shortest possible duration. Your doctor should monitor your condition regularly.

Use in children:

Diclo-XL 100 is not recommended for use in children.

If you take more Diclo-XL 100 than you should

If you accidentally take too many Diclo-XL 100 tablets, tell your doctor at once. If you can't do this, go to the nearest casualty department. Take along any tablets that are left, the container and the label so that the hospital staff can easily tell what medicine you have taken.

If you forget to take Diclo-XL 100

If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Diclo-XL 100

Continue to take the tablets for as long as your doctor tells you to. Talk to your doctor if you have any concerns.

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

4. Possible side effects

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

Serious side effects:

If you suffer from any of the following side effects, **STOP TAKING** the tablets and seek immediate medical help:

- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome
- Pass blood in your faeces (stools/motions)
- Pass black tarry stools
- Vomit any blood or dark particles that look like coffee grounds
- Indigestion or heartburn, abdominal pain (pains in your stomach) or other abnormal stomach symptoms.

Medicines such as Diclofenac may be associated with a small increased risk of heart attack (myocardial infarction) or stroke.

If you experience any of the following stop taking the tablets and contact your doctor immediately:

- All medicines can cause allergic reactions, although serious allergic reactions are very rare. Tell your doctor straight away if you get any sudden wheeziness, difficulty in breathing, swelling of the eye lids, face or lips, rash, reddening of the skin or itching (especially affecting your whole body)
- Severe painful skin disorder with blisters and peeling skin. You may also have flu-like symptoms such as fever or sore throat (Stevens-Johnson Syndrome)
- Jaundice with symptoms of yellowing of eyes and skin
- Diarrhoea (stop taking Diclo-XL 100 and do not take it again)
- Blood disorders; you may have a persistent sore throat or high temperature, anaemia (feeling tired after exercising, giddiness, looking pale)
- Respiratory problems: including inflammation of the lungs which causes breathlessness, cough and raised temperature and aggravated asthma
- An unexpected change in the amount of urine produced and/or its appearance.

The side effects listed below have also been reported

Common (may affect up to 1 in 10 people):

- Nausea, vomiting, wind, loss of appetite
- Headache, dizziness, vertigo
- Skin rash or spots
- Raised levels of liver enzymes in the blood.

Uncommon (may affect up to 1 in 100 people):

- Palpitations (fast or irregular heart beat)
- Chest pain
- Heart disorders, including congestive heart failure.

These symptoms are generally associated in those on long-term treatment with a high dose (150mg per day).

Rare (may affect up to 1 in 1,000 people):

- Gastritis (inflammation, irritation or swelling of the stomach lining)
- Drowsiness, tiredness
- Fluid retention, symptoms of which include swollen ankles
- Liver function disorders, including hepatitis
- Raised, itchy rash (Urticaria).

Very rare (may affect up to 1 in 10,000 people):

Effects on the nervous system:

Tingling or numbness in the fingers, tremor, blurred or double vision, hearing loss or impairment, tinnitus (ringing in the ears), sleeplessness, nightmares, mood changes, depression, anxiety, mental disorders, disorientation and loss of memory, fits, headaches together with a dislike of bright lights, fever and a stiff neck, impotence.

Effects on the stomach and digestive system:

Constipation, inflammation of the tongue, mouth ulcers, inflammation of the inside of the mouth or lips, taste changes, lower gut disorders (including inflammation of the colon or worsening of ulcerative colitis or Crohn's disease, inflammation of the pancreas (pain, feeling sick and being sick).

Effects on the heart, chest or blood:

Hypertension (high blood pressure), inflammation of blood vessels (vasculitis), hypotension (low blood pressure, symptoms of which include faintness, giddiness or lightheadedness).

Effects on the liver or kidneys:

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

Effects on skin or hair:

Skin rashes which may be made worse by exposure to sunlight. Hair loss, itching, facial swelling.

Not known (frequency cannot be estimated from the available data):

Confusion, hallucinations, malaise (general feeling of discomfort), inflammation of the nerves in the eye, disturbances in sensation, injury to the large intestine due to poor blood flow (ischaemic colitis).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Diclo-XL 100

Keep this medicine out of the sight and reach of children.

Store between 15°C and 25°C in a dry place.

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Do not use this medicine if you notice visible signs of deterioration.

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

6. Contents of the pack and other information

What Diclo-XL 100 contains

The active substance is diclofenac sodium. Each tablet contains 100mg diclofenac sodium.

The other ingredients are:

- Lactose (see section 2)
- Magnesium Stearate
- Hydrogenated vegetable oil type I USNF (Sterotex)
- Povidone K30
- Talc

What Diclo-XL 100 looks like and contents of the pack

Description: White, circular, biconvex tablets
Contents of pack: Prolonged release tablets; Packs of 28 tablets.

Marketing Authorisation Holder and Manufacturer

Strides Pharma UK Ltd.
Unit 4, Metro Centre, Tolpits Lane,
Watford, Herts,
WD18 9SS, UK
Tel: 01923 255580
Fax: 01923 255581

This leaflet was last revised in 12/2019.



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ARTWORK DETAIL LABEL

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Buyer/Country	Strides Pharma UK Ltd.	Component	Pack Insert
Dimension	180 x 280 mm	Pack	--
New Item Code	1039999	Old Item Code	1018504
Colour Shades	Black	No. of Colours	1
Change Control No.	PC-ODF/2019/342 Record Number: 237403		Artwork Version 2.0
Design/Style	Front & Back Printing. To be supplied in the unfolded size.		
Substrate	60 GSM paper.		
Special Instructions	PRINTING CLARITY TO BE CLEAR AND SHARP.		
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