PACKAGE LEAFLET: INFORMATION FOR THE USER

Vitafen 100 mg Film-coated Tablets

Aceclofenac

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. 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.

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1. WHAT VITAFEN IS AND WHAT IT IS USED FOR

Vitafen contains the active substance Aceclofenac. Aceclofenac belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). These drugs reduce inflammation and pain.

Vitafen is used to relieve pain and reduce redness and swelling (inflammation) in patients suffering from:

- arthritis of the joints (osteoarthritis)
- autoimmune disease that causes chronic inflammation of the joints (rheumatoid arthritis)
- arthritis of the spine which can lead to the fusion of the vertebrae (ankylosing spondylitis).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE VITAFEN

Do not take Vitafen

- if you are allergic to aceclofenac or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to aspirin or any other NSAIDs (such as ibuprofen, naproxen or diclofenac).
- if you have taken aspirin or any other NSAIDs and experienced one of the following:
  - asthma attack causing tightness in the chest, wheezing and difficulty breathing.
  - runny nose, itching and/or sneezing (irritation of the nose).
  - raised red circular patchy rash on the skin which may have felt or like a sting or burn.
  - a severe allergic reaction known asanaphylactic shock. The symptoms may be life threatening and include difficulty breathing, wheezing, abnormal pain and vomiting.

- if you have a history of, suffer from, or suspect that you have a stomach ulcer or have vomited blood or passed blood in your faeces (black tarry stools).
- if you have moderate to severe kidney disease.
- if 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.
- if you have or have had problems with your blood circulation (peripheral arterial disease)
- if you suffer from or suspect that you have severe liver failure.
- if you suffer from bleeding or any type of blood clotting disorders.
- if you are in the first or second trimester of pregnancy (unless considered essential by your doctor).
- if you are in the last 3 months of pregnancy.

This medicine contains less than 1mmol sodium (23 mg) per tablet, that is to say essentially 'sodium free'.

Vitafen is not recommended for use in children.

Warnings and precautions:
Talk to your doctor or pharmacist before taking Vitafen:
- if you suffer from any other form of kidney or liver disease.
- if you have any of the following disorders, as they may worsen:
  - disorders of the stomach or gut/bowel
  - inflammatory bowel disease (ulcerative colitis)
  - chronic inflammatory bowel disease (Crohn's disease)
  - ulceration, bleeding or perforation of the stomach or bowel
- if you have or have ever had problems with the circulation of the blood to your brain.
- if you suffer from asthma or any other breathing problems.
- if you suffer from a rare inherited blood disorder known as **porphyria.**
- if you smoke.
- if you have diabetes.
- if you have angina, blood clots, high blood pressure, raised cholesterol or raised triglycerides.
- if you suffer from an autoimmune condition known as systemic lupus erythematosus or other connective tissue disorders.
- if you are infected with chicken pox, the use of this medicine should be avoided because a rare serious infection of the skin may develop.
- if you are recovering from major surgery.
- if you are elderly (your doctor will prescribe you the lowest effective dose over the shortest duration).

Hypersensitivity reactions can occur and very rarely, very serious allergic reactions are appearing (see section 4. Possible side effects). The risk is higher in the first month of treatment. Vitafen should be stopped immediately at the first onset of symptoms such as tightness of the chest,

breathing difficulties, fever, skin rashes, soreness of the skin lining the mouth and other mucous membranes causing ulcers, or any signs of hypersensitivity.
Medicines such as Vitafen may be associated with an increased risk of heart attack ("myocardial infarction"). Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment.

Other medicines and Vitafen
Tell your doctor or pharmacist if you are taking, have recently or might take any other medicines.

Please tell your doctor if you are taking:

- medicines used to treat mental health problems like **depression** (selective serotoninreuptake inhibitors (SSRIs) such as citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine and sertraline) or manic depression (lithium)
- medicines used to treat **heart failure** and irregular heartbeats (cardiac glycosides such as digoxin)
- medicines used to treat **high blood pressure** (antihypertensives: ACE inhibitors such as enalopril, lisinopril; angiotensin II receptor antagonists such as losartan, candesartan; also hydralazine, methyldopa, clonidine, moxonidine, propranalol)
- medicines to treat infection **(quinolone antibiotics** such as ciprofloxacin, ofloxacin, levofloxacin moxifloxacin)
- drugs used to increase the rate of **urine excretion** (diuretics such as thiazides, furosemide, amiloride hydrochloride)
- medicines that stop **blood** clotting (anticoagulants) such as warfarin, heparin
- methotrexate which is used to treat **cancer** and **autoimmune** disorders such as arthritis and skin conditions
- mifepristone which is used as an emergency **contraceptive** or to induce **abortions**
- any **steroids** for the treatment of swelling and inflammation (glucocorticoids such as hydrocortisone, prednisolone)
- medicines used to suppress the **immune** system after organ transplant (cyclosporine or tacrolimus)
- medicines used to treat **HIV** (zidovudine)
- medicines used to lower **blood sugar** levels in diabetes (antidiabetics such as glibenclamide, glicazide, tolbutamine)
- any other painkiller **NSAID** drugs (aspirin, ibuprofen, naproxen, COX-2 inhibitors such as celecoxib and etoricoxib)

Vitafen with food and drink
Vitafen must be taken preferably with or after food.

Pregnancy, breast-feeding and fertility
Oral forms (e.g., tablets) of aceclofenac can cause adverse effects in your unborn baby. It is not known if the same risk applies to Vitafen.

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. Do not use Vitafen if you are in the last 3 months of pregnancy. You should not use Vitafen during the

first 6 months of pregnancy unless clearly necessary and advised by your doctor. If you need treatment during this period, the lowest dose for the shortest time possible should be used.

You should inform your doctor if you have problems becoming pregnant. NSAIDs may make it more difficult to become pregnant.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
If you are taking Vitafen and you experience dizziness, drowsiness, tiredness or any visual disturbances, you must not drive or use machinery.

3. HOW TO TAKE VITAFEN

Always take Vitafen exactly as your doctor or pharmacist has told you. You will be prescribed the lowest effective dose over the shortest duration to reduce side effects. Check with your doctor or pharmacist if you are not sure.

The recommended dose in adults is 200mg (two Vitafen tablets). One 100mg tablet should be taken in the morning and one in the evening.

Tablets should be swallowed whole with plenty of water and should be taken with or after food. Do not crush or chew the tablets.

Do not exceed the stated daily dose.

Elderly
If you are elderly, you are more likely to experience serious side effects (listed in section 4 'Possible Side Effects). If your doctor prescribes Vitafen for you, you will be given the lowest effective dose over the shortest duration.

If you take more Vitafen than you should
If you accidentally take too many Vitafen tablets, contact your doctor immediately or go to your nearest hospital casualty department. Please take this leaflet or the box the Vitafen tablets came in, with you to the hospital so that they will know what you have taken.

If **you forget to take Vitafen**
If you miss a dose, do not worry, just take the next dose at the usual time. Do not take a double dose to make up for a forgotten tablet dose.

If **you stop taking Vitafen**
Do not stop taking Vitafen unless your doctor advises you.

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.

Stop taking the medicine and seek medical advice **IMMEDIATELY** if you experience any of the following side effects:

- Severe allergic reaction (anaphylactic shock) - symptoms may develop quickly and can be life-threatening if not immediately treated and include fever, difficulty breathing, wheezing, abnormal pain,vomiting, swelling of the face and throat.
- Heart attack (myocardial infarction) or stroke, since medicines such as Vitafen may be associated with a slightly increased risk
- severe skin rashes such as Stevens-Johnnson Syndrome and Toxic Epidermal Necrolysis. These are potentially life-threatening and develop quickly forming large blisters and the skin to peel away. The rash can also appear in the mouth, throat or eyes. Fever, headache and aching of the joints usually occur at the same time.
- meningitis. The symptoms include high fever, headache, vomiting, blotchy red rashes, neck stiffness, sensitivity and intolerance to light.
- Kidney failure.
- Passing blood in your faeces (stools/motions)
- Passing black tarry stoolsvomit any blood or dark particles that look like coffee grounds.

STOP TAKING the medicine and seek medical advice if you experience:

- Indigestion or heartburn
- abdominal pain (pains in your stomach) or other abnormal stomach symptoms
- blood disorders such as reduced production of blood cells, abnormal breakdown of red blood cells known as haemolytic anaemia, low content of iron in the blood, low level of white blood cells, low number of platelet cells, increased blood potassium levels which can irritate the blood vessels causing inflammation known as vasculitis. These disorders can cause you to feel extremely tired, breathless, aching of the joints and be prone to repeated infections and bruising.

If any of the **below** side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

<u>Common</u> (occur in more than 1 in 100 patients but in less than 1 in 10 patients):

- dizziness • nausea (feeling sick) • diarrhoea • increased liver enzymes in the blood

<u>Uncommon</u> (occur in more than 1 in 1,000 patients but in less than 1 in 100

- wind (flatulence) • inflammation or irritation of the lining of the stomach (gastritis) • constipation • vomiting • mouth ulcers • itching • rash • inflammation of the skin (dermatitis) • raised circular red itchy, stinging or burning patches on the skin (hives) • increase in blood urea levels • increase in blood creatinine levels

<u>Rare</u> (occur in more than 1 in 10,000 patients but in less than 1 in 1,000 patients):

- low levels of iron in the blood • hypersensitivity (allergic reaction) • visual disturbance

- shortness of breath • heart failure • high blood pressure • bleeding from the stomach or bowel • stomach or bowel ulceration

Very Rare (occur in less than 1 in 10,000 patients):

- low white blood cells levels • low platelets levels in the blood • abnormal breakdown of red blood cells (anaemia) • high potassium levels in the blood • depression • strange dreams • inability to sleep • tingling, pricking or numbness of skin • uncontrollable shaking (tremor) • drowsiness • headaches • abnormal taste in the mouth • sensation of spinning when standing still • ringing in the ears • heart pounding or racing (palpitations) • hot flushes • difficulty
- high pitched noise when breathing • inflammation of the mouth • stomach ulcer • perforation of either the stomach, large intestine or bowel wall • worsening of colitis and Crohn's disease • inflammation of the pancreas (pancreatitis) • injury of the liver (hepatitis) • yellowing of the skin (jaundice) • spontaneous bleeding into the skin (appears as a rash) • blisters • nephrotic syndrome: a condition which indicates kidney damage and includes large amounts of protein in the urine, low blood albumin levels, high blood cholesterol levels and swelling of the legs, feet or ankles• water retention and swelling • tiredness • leg cramps • increased blood alkaline phosphatase levels • weight gain

Other side effects that have been reported with this type of drug (NSAIDs) are:

- hallucinations
- confusion
- blurred, partial or complete loss of vision
- painful movement of the eye
- worsening of asthma
- skin reaction to sunlight
- inflammation of the kidneys
- generally feeling unwell

Exceptionally, serious skin infections occur in association with chickenpox

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 to HPRA Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2; Tel: +353 I 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE VITAFEN

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

Do not store above 25°C.

Store in the original pack in order to protect from light.

Do not use this medicine after the expiry date which is stated on the outer carton and on the blister pack after EXP. The expiry date refers to the last day of that month.

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Vitafen contains
The active substance is Aceclofenac. Each tablet contains 100mg of Aceclofenac.
The other ingredients are:
Tablet core: cellulose microcrystalline (Avicel PH 101), croscarmellose sodium, povidone K30 and glycerol distearate (Type I).
Film-coating: hypromellose, titanium dioxide and polyethylene glycol 400.

What Vitafen looks like and contents of the pack
Vitafen Tablets are round, white tablets and have the text "100" marked on one side.
They are film-coated tablets.
Vitafen Tabletsare available in blister packs of 10, 20, 30, 40, 60 or 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer Marketing Authorisation Holder:
Phoenix Labs,
Suite 12, Bunkilla Plaza, Bracetown Business Park, Clonee, Co. Meath, Ireland.
Manufacturer: Benta Lyon, 29 Avenue Charles de Gaulle, 69230 ST GENIS LAVAL, France
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