

PACKAGE LEAFLET: INFORMATION FOR THE USER

Otriflu 12.5 mg film coated tablets

Diclofenac potassium

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

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- You must consult your doctor if your symptoms worsen or do not improve.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.
- In this leaflet, Otriflu 12.5 mg film coated tablets will be called Otriflu tablets.

In this leaflet

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1. What Otriflu tablet is and what it is used for

What Otriflu tablet is

Otriflu 12.5 mg film coated tablets contain diclofenac which belongs to a group of medicines called “non-steroidal anti-inflammatory drugs” (NSAIDs). Otriflu tablets are pain relievers which also reduce inflammation (swelling) and lower body temperature.

What Otriflu tablets is used for

Otriflu tablets provide fast relief from:

- Headache, dental pain, period pain, rheumatic and muscular pains, backaches.
- Symptoms of colds and flu (including aches and pains, sore throat pain). They also reduce fever.

How Otriflu tablets work

Otriflu tablets relieve the symptoms of inflammation, such as pain and swelling, by blocking the synthesis of the molecules (prostaglandins) responsible for inflammation, pain and fever, it has no effect on the causes of inflammation or fever.

If you have any question about how Otriflu tablets works, or why it has been prescribed for you, ask your doctor or pharmacist.

You must contact a doctor if your symptoms worsen or do not improve within 5 days in case of pain or 3 days in case of fever.

2. Before you take Otriflu tablets

Follow the instructions given to you by your doctor or pharmacist carefully, even if they differ from the general information contained in this leaflet.

Do not take Otriflu tablets if you:

- **are allergic** to diclofenac or any of the other ingredients of this medicine listed in Section 6 and at the end of section 2
- **have ever had** an allergic reaction to medicines used to treat pain, inflammation or fever, such as diclofenac, aspirin, ibuprofen or a cyclo-oxygenase-2 selective inhibitor (COX2) like celecoxib. Reactions may include: asthma, wheezing, skin rash, face swelling, runny nose. If you are not sure, ask your doctor or pharmacist.
- **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.
- **have or have had** problems with your blood circulation (peripheral arterial disease)
- **have or had** a stomach (gastric) or intestinal (peptic) ulcer, bleeding or perforation which may show up as severe indigestion.
- **had** gastrointestinal bleeding or perforation related to previous NSAIDs therapy
- **have** ever noticed blood in your stools or black stools (symptoms of gastrointestinal bleeding).
- **suffer** from severe liver or kidney disease.
- **suffer** from, liver failure or kidney failure.
- **are** in the last three months of pregnancy.

If any of the above apply to you, do not take Otriflu tablets and tell your doctor. Your doctor will decide whether the tablets are suitable for you.

Warnings and precautions:

Talk to your doctor or pharmacist before taking Otriflu tablets if you:

- are taking Otriflu tablets at the same time as other anti-inflammatory medicines including aspirin, corticosteroids, 'blood thinners' or anti-depressants called selective serotonin reuptake inhibitors (SSRIs) (see Taking other medicines).
- suffer from asthma, hayfever, or chronic respiratory diseases.
- have ever had any gastrointestinal problems such as an ulcer, bleeding or black stools, or have experienced stomach discomfort or had heartburn after taking anti-inflammatory medicines in the past.
- suffer from any stomach or bowel disorder, for example ulcerative colitis or Crohn's disease.
- have liver or kidney problems.
- could be dehydrated (e.g. through sickness, diarrhoea, before or after major surgery).
- have swollen feet.
- suffer from a bleeding disorder or any other blood disorder, including a rare

condition called hepatic porphyria.

- suffer from systemic lupus erythematosus (SLE) or mixed connective tissue disease (MCTD).

Make sure your doctor or pharmacist knows, before you take diclofenac

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

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

If any of these apply to you, do not use Otriflu tablets before talking to your doctor or pharmacist.

Other Precautions

- Medicines such as Otriflu tablets 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.
- If, at any time while taking Otriflu 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, contact your doctor immediately.

If you have heart problems such as ischaemic heart disease, peripheral arterial disease, cardiovascular disease or congestive heart failure, had a previous stroke or think you may be at risk of these conditions (e.g. you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.

Monitoring of blood count is recommended during prolonged treatment with Otriflu tablets. If you have defects of haemostasis (problem stopping bleeding), you should be monitored during your treatment with Otriflu tablets.

Otriflu tablets may impair kidney function. Monitoring of kidney function is recommended before or after surgery as a precautionary measure.

- Otriflu tablets may reduce the symptoms of an infection (e.g. headache, high temperature) and may therefore make it more difficult to detect. If you feel unwell and need to see a doctor, remember to tell them that you are taking Otriflu tablets.
- In very rare cases, Otriflu tablets, like other anti-inflammatory medicines, may cause severe allergic skin reactions (e.g. rash, lesions across face, arms and legs) which may be related to a serious illness with blistering of the skin, mouth, eyes and genitals (Steven Johnsons Syndrome). Therefore, inform your doctor immediately if you experience such reactions.
- Diclofenac belongs to a group of medicines which may make it more difficult to become pregnant. This effect is reversible on stopping the medicine. You should not take Otriflu tablets unless necessary if you are planning to become pregnant or if you have problems becoming pregnant.

Children and adolescent (under 14 years of ages)

Do not give Otriflu tablets to children and adolescents under 14 years of age.

Taking other medicine

It is particularly important to tell your doctor or pharmacist if you are taking any of the following medicines:

- Lithium or a class of antidepressant drugs called selective serotonin-reuptake inhibitors (SSRIs) (medicines used to treat depression).
- Cardiac glycosides, a class of drug e.g. digoxin used to treat heart problems.
- ACE inhibitors or beta-blockers (classes of medicine used to treat high blood pressure or heart failure).
- Diuretics (medicines which increase the amount of urine).
- Medicines used to treat diabetes (except insulin)
- Other pain relievers such as aspirin, ibuprofen or naproxen (includes cyclo-oxygenase-2 selective inhibitors (COX2) like celecoxib).
- Corticosteroids (for relief of inflamed areas of the body).
- Anticoagulants (blood thinning tablets like warfarin).
- Antiplatelet agents (e.g. aspirin).
- Methotrexate (used to treat some kinds of cancer or arthritis).
- Ciclosporin, tacrolimus (immunosuppressant drugs for patients who have received organ transplants).
- Trimethoprim (a medicine used to prevent or treat urinary tract infections)
- Some medicines used against infection (quinolone antibacterials).
- Zidovudine (used in the treatment of HIV infection)
- Sulfapyridine (a medicine used to treat gout) or voriconazole (a medicine used to treat fungal infections).
- Phenytoin (a medicine used to treat seizures).
- Colestipol and cholestyramine (medicines used to regulate cholesterol).

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Taking Otriflu tablets with food and drink

The tablets should be swallowed whole with a drink of water, preferable with or after food.

Elderly

Elderly people may react more strongly to Otriflu tablets than other adults. They should follow their doctor's instructions particularly carefully and use the lowest number of tablets which provide relief of symptoms. It is especially important for elderly patients to report unwanted effects promptly to their doctor.

Pregnancy

If you are pregnant or think that you may be pregnant, **tell your doctor.**

As with other anti-inflammatory medicines, you must not take Otriflu tablets at all during the last 3 months of pregnancy, as it could harm your unborn child or cause problems at

delivery. You should not take Otriflu tablets during the first 6 months of pregnancy unless absolutely necessary.

Breast-feeding

Tell your doctor if you are breast-feeding. You should not take Otriflu tablets if you are breast-feeding as it might be harmful for your infant.

Ask your doctor or pharmacist for advice before taking any medicine during pregnancy or breast-feeding.

Fertility

As with other anti-inflammatory medicines, the use of diclofenac, the active substance in Otriflu tablets, may make it more difficult to become pregnant. This is reversible on stopping the medicine. You should however inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

Driving and using machines

Usually this medicine has no influence on the ability to drive or use machines. However, in rare cases you may experience vision disorders, dizziness or drowsiness. If you notice such effects, do not drive or use machines. Tell your doctor as soon as possible.

Important information about one of the ingredients

Otriflu tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, or have rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption contact your doctor before taking this medicine.

3. How to take Otriflu tablets

How much Otriflu tablets to take

Do not take more than the recommended dose. It is important that you use the lowest dose that controls your pain and that you do not take Otriflu tablets for longer than necessary.

For adults and adolescents aged 14 years and over

Take an initial dose of 2 tablets when symptoms appear. If needed, continue with 1 or 2 tablets every 4 to 6 hours. Do not take more than 6 tablets in 24 hours. Do not take Otriflu tablets for more than 5 days for relief of pain and 3 days for relief of fever.

How to take Otriflu tablets

- Swallow the whole tablet with a drink of water.
- The tablet should be taken with or after food.

How long to take Otriflu tablets

It is important that you take the lowest dose to control your symptoms and that you do not take the tablets for longer than necessary. Your doctor will tell you exactly how many tablets to take, and for how long. Do not exceed the recommended dose and duration of treatment. If symptoms persist or worsen, tell your doctor to ensure that they are not due to a serious illness. Do not take more than the recommended dose.

If you take more Otriflu tablets than you should

If you accidentally take more tablets than recommended, **tell your doctor or pharmacist or go to your nearest hospital casualty department immediately.** Take your medicine with you.

If you forget to take Otriflu tablets

If you miss a dose, take the next dose as soon as you remember. If it is nearly time for your next dose, take the next tablet at the usual time. Do not take a double dose to make up for a forgotten tablet.

4. Possible side effects

Like all medicines, Otriflu tablets can cause side effects, although not everybody gets them. If you experience any of the side-effects, stop taking Otriflu tablets and go to a doctor or the hospital straightaway.

Some side effects could be serious

Mild cramping and tenderness of the abdomen, starting shortly after the start of the treatment with diclofenac potassium 12.5mg Film-Coated Tablets and followed by rectal bleeding or bloody diarrhoea usually within 24 hours of the onset of abdominal pain (frequency not known, cannot be estimated from the available data).

Some **uncommon** (*may affect between 1 and 10 in every 1000 people*) side effects, especially when taking high daily dose (150mg) for a long period of time. The frequency is expected to be lower for short-term treatment with low dose (up to 75mg daily).

- Palpitations, sudden and oppressive chest pain (signs of myocardial infarction or heart attack).
- Breathlessness, difficulty of breathing when lying down, swelling of the feet or legs (signs of cardiac failure).

Some rare (*may affect up to 1 in every 1000 people*) **or very rare** (*may affect up to 1 in every 10,000 people*) **side effects could be serious.**

- Severe stomach pain, bloody or black stools. Vomiting blood, bloody diarrhoea. These may be sign and symptoms of ulceration, bleeding and perforation of the stomach or intestines.
- Allergic reaction including difficulty of breathing or swallowing, swelling of the face, lips, mouth, tongue or throat often associated with rash and itching, which may cause difficulty to swallow, hypotension (low blood pressure), fainting.
- Sudden difficulty of breathing and feeling of tightness in chest with wheezing or coughing (signs of asthma).
- Sudden and severe headache, nausea, dizziness, numbness, inability to speak or difficulty in speaking, paralysis (signs of stroke).
- Stiff neck (sign of aseptic meningitis).
- Red or purple skin (possible signs of blood vessel inflammation), skin rash with blisters, blistering of the lips, eyes and mouth, skin inflammation with flaking or peeling.

- Any change in the appearance or amount of urine, for example blood in urine, excess of protein in the urine, severe decreased urine output (signs of kidney disorders).
- Swelling of arms, hands, legs and feet (oedema).
- Yellowing of the skin or eyes (signs of hepatitis/liver inflammation), increased liver enzymes.
- Unusual bleeding or bruising, frequent infections.
- Breathlessness, tiredness, swollen feet and ankles (signs of heart failure).
- Convulsions.
- Hypertension (high blood pressure).
- Increased sensitivity of the skin to the sun.

Medicines such as diclofenac may be associated with a small increased risk of heart attack (also called “myocardial infarction”) or stroke. Any risk is more likely with high doses and prolonged treatment.

If you experience any of these, **stop taking this medicine and tell a doctor straightaway.**

Other side effects

Other side effects which may occur are usually mild. Some of the effects have been reported with higher doses of diclofenac, the active substance in Otriflu, used for longer duration. **If you find these are troubling you, talk to a doctor or pharmacist.**

Some side effects are common (*may affect up to 1 in every 10 people*)

- Headache, dizziness
- Nausea, vomiting, diarrhoea, indigestion, abdominal pain, flatulence
- Loss of appetite
- Change in liver function (e.g. level of transaminases)
- Skin rash
- Vertigo

Some side effects are rare (*may affect up to 1 in every 1000 people*)

- Drowsiness
- Stomach pain
- Swelling of arms, hands, legs and feet (oedema)
- Hypotension and shock (symptoms of anaphylactic and anaphylactoid reaction)
- Shortness of breath (symptom of asthma)
- Gastrointestinal bleeding, stomach and intestine ulcer (with or without bleeding or perforation), bloody or black stools
- Yellowing of the skin (Liver disorder)
- Inflammation of the colon (colitis)
- Hives (urticaria)

Some side effects are very rare (*These side effects may affect less than 1 in every 10,000 people*)

- Disorientation, memory impairment
- Depression, irritability, psychotic disorder, anxiety, trembling
- Difficulty sleeping, nightmare
- Tingling or numbness of the hands or feet

- Taste disorders, upper abdominal cramp
- Vision and hearing disorders
- Constipation, mouth sores, swollen, red and sore tongue, ulcer of the oesophagus (the tube that carries food from the throat to the stomach)
- Hair loss
- Redness, swelling and blistering of the skin (due to increased sensitivity to sun)
- Blood disorders including reduction in blood platelets, which increases the risk of bleeding or bruising (Thrombocytopenia), decrease in the number of white blood cells, which increases the risk of infection (leukopenia), reduction in the number of red blood cells which can make the skin appear yellow and cause weakness or breathlessness (haemolytic anemia), the bone marrow not able to produce enough new blood cells to replace old blood cells (aplastic anaemia), severe reduction in number of white blood cells which makes infections more likely (agranulocytosis)
- Tinnitus (ringing in the ear)
- Aseptic meningitis
- Worsening of Crohn's disease (swelling of the intestine affecting any part from mouth to anus) or ulcerative colitis (inflammation of the lining of the large intestine and rectum)
- Pancreatitis (swelling of the Pancreas, which causes severe pain in the abdomen and back)
- Diaphragm-like intestinal strictures (the narrowing of the intestine)
- Hepatic (Liver) failure

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 HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 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 Otriflu tablets

- **Keep this medicine out of the sight and reach of children.**
- Do not use this medicine after the expiry date which is shown on the end of the carton and on the blister. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Content of pack and other Information

What Otriflu tablets contains

- The **active substance** of Otriflu tablets is diclofenac potassium. Each tablet contains 12.5 mg of diclofenac potassium.
- The **other ingredients** are Silica, lactose, maize starch, sodium starch glycolate, povidone, magnesium stearate, microcrystalline cellulose, hypromellose, titanium dioxide (E171) and stearic acid.

What Otriflu tablets looks like and contents of the pack

- Otriflu 12.5 mg film coated tablets are small, easy-to-swallow, white film-coated tablets. They are available in packs of 10 and 20 tablets.

Marketing authorisation holder

GlaxoSmithKline Consumer
Healthcare (Ireland)
Limited
CityWest Business Campus,
Dublin 24,
Ireland.

Manufacturer

Novartis Farmcèutica SA
Barberà del Vallès
Spain

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