PACKAGE LEAFLET: INFORMATION FOR THE USER
Drogenil 250mg Tablets
flutamide

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 or pharmacist.
- 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 the side effects, talk to your doctor or pharmacist this includes any side effects not listed in this leaflet.

What is in this leaflet:

1. WHAT DROGENIL IS AND WHAT IT IS USED FOR

Drogenil 250mg Tablets contain flutamide, which is a medicine called an 'antiandrogen'.
These medicines stop the effects of male sex hormones which is important in the treatment of conditions that react to male sex hormones.

Drogenil 250mg Tablets is used for the treatment of certain types of prostate cancer. The prostate is a walnut shaped gland found next to the bladder.

Prostate cancer leads to uncontrolled growth of the prostate. This forms a tumour and causes symptoms such as:

- difficulty in passing urine
- passing urine more frequently than usual, especially at night
- blood in the urine
- pain on passing urine

Prostate cancer may also spread to the bones causing pain in the back, hips or pelvis.

Prostate cancer is dependent on the male sex hormones for growth. By stopping the effects of male sex hormones it is possible to slow down or shrink the tumour both in the prostate and the areas it has spread to. This is why you have been given Drogenil.

It may also be prescribed with other drugs that block male sex hormones called LHRH (luteinising hormone releasing hormone) agonists, for example goserelin or leuprorelin or after orchidectomy, an operation on the testes.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DROGENIL 250mg TABLETS

Do not take Drogenil

- If you are allergic to flutamide or to any of the other ingredients OF this medicine (listed in section 6).

Warnings and precautions

- If you are currently taking steroids or a blood thinning drug containing an anticoagulant, or theophylline for a breathing problem, you should tell your doctor before starting Drogenil.
- Inform your doctor if you have or have had any problem concerning your liver, kidney, blood vessels or heart (heart condition called 'long QT syndrome' or family history of this heart condition), have low bone mineral density, or have low red blood cell count (anaemia) since Drogenil may not be appropriate for you. You may be asked to have liver tests occasionally or the dosage of Drogenil may need to be adjusted.
- If you have oedema or ankle swelling, you should talk to your doctor before taking Drogenil as it can make these conditions worse.
- If you are on long term treatment with Drogenil your sperm count may need to be checked.
- If you have a particular enzyme deficiency (G-6-P), you may be pre-disposed to problems with delivery of oxygen to tissues
- If you have diabetes and you are also in treatment with a type of medicine called 'LHRH agonist' (e.g., goserelin, leuproprelin) it may be necessary to monitor your blood glucose levels more frequently.
- Tell your doctor if you have or may have any risk of having osteoporosis since you may need additional investigations.

Other medicines and Drogenil

Tell your doctor if you are taking, have recently taken or might take any other medicines. In particular you should tell your doctor or pharmacist if you are taking any of the following medicines:

- Steroids.
- Oral anticoagulants, used to thin the blood.
- Theophylline, to relieve or prevent symptoms of asthma and bronchospasm.
- Any medicines that are toxic to the liver.
- Medicines that may affect the heart's rhythm such as certain medicines used to treat irregular heartbeat, mental illness, depression, pain (e.g., narcotics), infections (e.g., bacterial, malarial, fungal), nausea and vomiting associated with cancer treatment or surgery, or breathing conditions (e.g., asthma, chronic lung disease such as COPD)

Drogenil with food and drink

You should avoid taking excessive alcohol whilst you are being treated with Drogenil.

Pregnancy, breast-feeding and fertility

Drogenil is intended only for use in male patients. Contraceptive measures should be taken during treatment.

Flutamide may cause foetal harm if taken by pregnant women. Tell your doctor if you are or think you may be pregnant, or if you are breast-feeding as flutamide may be present in breast milk.

Driving and using machines

Possible side effects such as tiredness, dizziness and confusion have been reported and may impair the ability to drive and use machines. Do not drive or use machinery if affected by these side effects.

Important information about some of the ingredients of Drogenil
Drogenil 250mg Tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE DROGENIL 250mg TABLETS

Always take Drogenil exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
The usual dose is one tablet three times daily at 8 hour intervals. The tablets should be swallowed with a glass of water.
If you have also been prescribed an LHRH (luteinising hormone-releasing hormone) agonist such as goserelin or leuprorelin, it is best to start taking Drogenil at the same time or 24 hours before starting the LHRH agonist.
If you are also having radiation therapy, you should start taking Drogenil 8 weeks before starting therapy and then keep taking the tablets throughout your course of treatment.
If you have liver problems, long term treatment with Drogenil will be assessed for its benefit by your doctor.

If you take more Drogenil than you should
If you (or someone else) takes too much Drogenil by mistake, you should contact your doctor immediately.

If you forget to take Drogenil
If you forget to take your medicine, take your recommended dose as soon as you remember and then carry on as normal. Do not take a double dose to make up for the forgotten dose.

If you have 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.

Hypersensitivity (allergic) reactions can occur with any medicine. Therefore, if you experience any of the common symptoms of an allergic reaction such as swelling (of the face, lips, tongue and/or throat), trouble breathing or swallowing, wheezing, itching, hives and/or skin rash, contact your doctor right away.

You should tell your doctor if you notice any unusual changes to your breasts.

The following side effects have been reported when Drogenil tablets are taken alone:
Very common (may affect more than 1 in 10 people)

- Gynecomastia (enlarged breasts) and/or breast tenderness, galactorrhea (secretion of breast milk)

Common (may affect up to 1 in 10 people)

- Increased appetite
- Insomnia (trouble sleeping)

- Diarrhoea, nausea, vomiting
- Transient abnormal liver function and Hepatitis (inflammation of the liver)
- Tiredness

Rare (may affect up to 1 in 1,000 people)
- Herpes zoster (shingles)
- Edema (swelling), ecchymosis (bruising), lymphedema (swelling of the arms or legs)
- Lupus-like syndrome (facial rash and/or joint aches)
- Anorexia (poor appetite)
- Anxiety (nervousness), depression (sadness)
- Dizziness, headache
- Blurred vision
- Abdominal disorders without clear causes, upset stomach, ulcer-like pain, heartburn, constipation
- Pruritus (itching)
- Decreased libido (reduced sex drive)
- Reduced sperm counts
- Weakness, malaise (feeling unwell), thirst, chest pain
- Hot flushes

Very rare (may affect up to 1 in 10,000 people)
- Male breast neoplasm (tumour)
- Photosensitivity reactions (sensitivity to light)

The following side effects have been reported when Drogenil tablets are taken at the same time as an LHRH agonist:

Very Common (may affect more than 1 in 10 people)
- Diarrhoea, nausea, vomiting
- Decreased libido (sex drive), impotence
- Hot flushes

Uncommon (may affect up to 1 in 100 people)
- Hepatitis (inflammation of the liver)

Rare (may affect up to 1 in 1,000 people)
- Anaemia (decreased red blood cells), leucopoenia (decreased infection-fighting white blood cells), thrombocytopenia (decreased platelets)
- Anorexia (poor appetite)
- Depression (sadness), anxiety (nervousness)
- Drowsiness, confusion, nervousness, numbness
- Gynecomastia (enlarged breasts)
- Hypertension (high blood pressure)
- Abdominal disorders without clear causes
- Jaundice (yellowing of the skin and/or whites of the eyes)
- Rash
- Neuromuscular (nervous system or muscular) symptoms
- Genitourinary tract (problems with the kidneys or urinary bladder) symptoms
- Injection site irritation and rash, edema (swelling)

- Changes in liver function, elevated blood urea nitrogen (BUN), elevated serum creatinine (elevations in kidney tests)

Very rare (may affect up to 1 in 10,000 people)
- Male breast neoplasm (tumour)
- Oedema (swelling), haemolytic anaemia (destruction of red blood cells), macrocytic anaemia (low red blood cell counts associated with large red blood cells), methemoglobinemia (decreased ability of red blood cells to carry oxygen), sulfhemoglobinemia (decreased ability of red blood cells to carry oxygen), megalocytic anemia (low red blood cell counts associated with changes in white blood cell shapes)
- Hyperglycemia (high blood sugar), aggravation of diabetes
- Lung symptoms (e.g. dyspneoa (shortness of breath)) Interstitial lung disease (diseases affecting the spaces around the air sacs in the lung)
- Cholestatic jaundice (yellow skin and/or eyes caused by blockage in the liver), hepatic encephalopathy (confusion caused by liver malfunction), hepatic necrosis (death of liver cells), cases of death following severe hepatic injury.
- Photosensitivity reactions (sensitivity to light), erythema (redness of the skin), ulcerations (skin breakdown), bullous eruptions (bubbles in the skin), epidermal necrolysis (death of skin cells)
- Change in urine colour to amber or yellow-green

Not known (frequency cannot be estimated from the available data)
- Thromboembolism (blood clot)

Micronodular alterations (bumps) of the body of breast can uncommonly occur.

An increase in serum testosterone is initially possible during monotherapy with flutamide; in addition, hot flushes and changes in hair character can occur.

Following the marketing of flutamide, cases of acute renal (kidney) failure, interstitial nephritis (inflammation in the area around kidney cells), and myocardial ischemia (inadequate oxygen delivery to the heart) have been reported with frequency unknown.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie

5. HOW TO STORE DROGENIL 250mg TABLETS

There are no special storage requirements for your medicine.

As with all medicines, keep out of the reach of children.

Do not take this medicine after the date which is stamped on the pack.

Do not throw away any medicines via waste water 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 Drogenil 250mg tablets contain
The active substance is flutamide
The other ingredients are lactose monohydrate, Sodium laruilsulfate, microcrystalline cellulose, maize starch, silica gel, and magnesium stearate

What Drogenil 250mg tablets look like and contents of the pack
Drogenil 250mg Tablets are round and pale yellow, with a groove on one side and the SP logo on the other. The tablets are available in blister packs containing 84 tablets.

Marketing Authorisation Holder Marketing Authorisation Holder:
Merck Sharp & Dohme Ireland (Human Health) Limited
Red Oak North,
South County Business Park,
Leopardstown, Dublin 18,
Ireland

Manufacturer:
Schering-Plough Labo N.V.
Heist-op-den-Berg
Belgium

This leaflet was last approved in April 2016.