

## Package leaflet: Information for the patient

### Metopirone 250 mg, soft capsules metyrapone

**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 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet

1. What Metopirone is and what it is used for
2. What you need to know before you take Metopirone
3. How to take Metopirone
4. Possible side effects
5. How to store Metopirone
6. Contents of the pack and other information

#### 1. What Metopirone is and what it is used for

Metopirone contains 250 mg of metyrapone. Metyrapone belongs to a group of medicines known as tests for pituitary function evaluation. Metyrapone is used as a diagnostic test to identify if you have an insufficient level of ACTH, a hormone secreted by the pituitary gland which controls cortisol secretion; or Metyrapone may be used to help diagnose a specific type of Cushing's syndrome.

The medicine can also be used to treat the signs and symptoms of endogenous Cushing's syndrome by lowering the elevated levels of cortisol (a hormone produced by the adrenal glands). Cushing's syndrome is a set of symptoms resulting from high levels of the hormone cortisol produced in your body by the adrenals.

#### 2. What you need to know before you take Metopirone

##### **Do not take Metopirone as a diagnostic test for ACTH insufficiency**

- If you suffer from a condition whereby your adrenal glands do not produce enough steroid hormones, cortisol or aldosterone, known as Addison's disease.

##### **Do not take Metopirone**

- if you are allergic to metyrapone or any of the other ingredients of this medicine listed in section 6.

#### Warnings and precautions

##### **Talk to your doctor before taking Metopirone for a diagnostic test if**

- you have, or think you may have, a condition in which your hormone levels are low (e.g. reduced adrenal gland production of cortisol or severe hypopituitarism). Your doctor

- will need to perform a test to make sure Metopirone is right for you.
- you have liver disease or damage to the liver, as this may cause the medicine to work more slowly.
- you are taking any medicines such as glucocorticoids as your doctor may decide to not do the Metopirone test as you will need to stop taking these.

### **During treatment with Metopirone**

Metopirone may temporarily lower the amount of hormones produced by your adrenal gland (cortisol) but your doctor will correct this using appropriate hormone medication.

If you have Cushing's syndrome, your doctor may also give you medicine to prevent infections developing. But if you develop shortness of breath and fever over hours or days, contact your doctor as soon as possible as you may be developing a serious lung infection.

### **Tests before and during treatment with Metopirone**

Your doctor will test your blood before you start the treatment and regularly during the treatment. This is to detect any possible abnormalities in your potassium levels and also to measure the levels of cortisol. Depending on the results, your doctor may adapt the dosage and/or prescribe a corrective treatment.

Depending on your cardiac risk factors, your doctor may decide to perform an ECG before the initiation or during treatment with Metopirone.

Talk to your doctor if you experience any of the following symptoms: weakness, fatigue, dizziness, loss of appetite, nausea or vomiting, diarrhoea, abdominal pain. These symptoms and also low blood pressure, high levels of potassium, low levels of sodium or low levels of glucose in the blood may be signs of hypocortisolism (insufficient levels of cortisol in the blood).

Your doctor will therefore check your blood pressure and perform a blood test. If you are diagnosed with hypocortisolism, your doctor may decide to temporarily administer a steroid (glucocorticoid) replacement therapy and/or reduce the dose or interrupt the treatment with Metopirone.

### **If you take Metopirone for a long time**

Your blood pressure may increase when taking this medicine.

### **Other medicines and Metopirone**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines as they may influence the results of the test with this medicine. The following medicines may affect the results of the Metopirone test:

- Anticonvulsants used to control epilepsy (e.g. phenytoin, barbiturates)
- Anti-depressants and neuroleptics used to treat anxiety, depression or psychiatric problems (e.g. amitriptyline, chlorpromazine, alprazolam)
- Hormones that affect the hypothalamo-pituitary axis which regulate many body processes such as stress, emotions, energy levels, digestion and the immune system (e.g. cortisol, hydrocortisone, ACTH, tetracosactin)
- Corticosteroids
- Antithyroid agents used to treat thyroid conditions (e.g. thyroxine, liothyroxine, carbimazole)
- Cyprohepatadine used to treat allergies (e.g. Periactin)

Metopirone should not be taken with paracetamol without consulting your doctor.

### **Pregnancy, breast-feeding and fertility**

### *Use in pregnancy*

Metopirone is not recommended in women of childbearing potential who are not using contraception.

If you are pregnant, think you are pregnant or are planning to become pregnant, talk to your doctor as soon as possible to know if you should stop or continue Metopirone.

If you have to take the medicine during pregnancy, your doctor will need to monitor your baby's cortisol levels for the first week of its life.

### *Use in breast-feeding*

Breast-feeding should be discontinued during treatment with Metopirone as there is a possibility that metyrapone may be passed to your baby in breast milk.

### **Driving and using machines**

If you feel dizzy or drowsy after taking this medicine, you should not drive or operate machinery until these effects have passed.

**Metopirone contains sodium parahydroxybenzoates (E215) and sodium propylparahydroxybenzoate (E217) which may cause allergic reactions (possibly delayed).**

### **Metopirone contains sodium**

This medicine contains less than 1 mmol (23 mg) per capsule. It is essentially 'sodium free'.

### **Monitoring and supervision**

When used as a diagnostic test, you should only be given this medicine when a healthcare professional is present, as they will need to monitor your body's responses to the medicine.

## **3. How to take Metopirone**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. If you are being given Metopirone to diagnose Cushing's Syndrome, you will need to go into hospital for some tests.

### **Use in adults**

#### **If you are having a short single-dose test (to test pituitary function):**

You will be asked to swallow the capsule(s) with yoghurt or milk at about midnight. You will then have a blood sample taken in the morning which will be reviewed by the doctor. The recommended dose is

30 mg/kg. The same dose is used in children.

#### **If you are having a multiple-dose test (to test pituitary function and to help diagnose a specific type of Cushing's syndrome):**

Your doctor will start taking samples of your urine 24 hours before you are given this medicine. You will then be given 2-3 capsules (500 – 750 mg) every 4 hours for the next 24 hours. You should take the capsules with milk or after a meal. Your doctor will then take more urine samples over the next 24 hours.

#### **If you are treated for the signs and symptoms of endogenous Cushing's Syndrome**

The dose you are given will be specific to you and may range from 1 capsule (250 mg) to 24 capsules (6 g) per day in three or four divided doses. The Metopirone dose may be periodically adjusted by your doctor with the aim to restore normal cortisol levels.

You should always follow the doctors' instructions closely and never change your dose unless your

doctor tells you to.

### **Use in children**

For the multiple-dose test children should be given 15 mg/kg with a minimum dose of 250 mg every 4 hours.

For management of Cushing's syndrome, the dose should be adjusted on an individual basis as a function of cortisol levels and tolerability.

### **If you take more Metopirone than you should**

If you take too many capsules, tell your doctor or nurse immediately, or go to your nearest Casualty Department. You may feel sick and have stomach ache and/or diarrhoea. You may also feel dizzy, tired, have a headache, begin sweating and your blood pressure increase. You may need to take activated charcoal and be given hydrocortisone.

### **If you forget to take Metopirone**

If you accidentally forget to take a dose of capsules, you should take it as soon as you remember. If it is nearly time for your next dose, do not double up your dose to make up for the one you have missed, but carry on taking your capsules as usual.

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.

### **Some side effects may be serious:**

- Tell your doctor immediately if you have two or more of these symptoms: weakness, light-headedness, fatigue, lack of appetite, nausea, vomiting, abdominal pain, diarrhoea. This may indicate that you have adrenal insufficiency (low cortisol levels). Adrenal insufficiency occurs when metyrapone lowers the amount of cortisol too much. It is more likely to occur during periods of metyrapone dosage increase or increased stress. Your doctor will correct this by using a hormone medicine to compensate lack of cortisol and/or by adjusting the dose of metyrapone.
- Tell your doctor immediately if you have bleeding or bruising lasting longer than normal, blood seen in the gums, nose or skin and feeling tired most of the time. This may indicate that you have a decrease of amount of red blood cells and/or white blood cells and/or platelets in blood.

See also Section 2 "During treatment with Metopirone".

### **Side effects by frequency:**

Very common side effects (may affect more than 1 in 10 people)

- Adrenal insufficiency (low cortisol levels)
- Loss of appetite
- Headache
- Dizziness (light-headedness)
- High blood pressure (hypertension)
- Nausea (feeling sick)
- Abdominal (stomach) pain
- Diarrhoea
- Skin allergic reaction (urticaria, rash (skin redness), itching)

- Joint pain
- Swelling of limbs, hands or feet
- Asthenic conditions (tiredness, fatigue)

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

- Low level of potassium (hypokalaemia)
- Feeling tired or sleepy
- low blood pressure (hypotension)
- Vomiting
- Acne
- Excessive hair growth in unusual areas (hirsutism)
- Muscular pain

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

- Abnormal liver function (hepatic enzymes increased)
- Leukopenia, anaemia, thrombocytopenia (decrease of amount of red blood cells, white blood cells or platelets in blood)
- Alopecia (hair loss)
  - Pulmonary infection

### **Reporting of side effects**

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, website: [www.hpra.ie](http://www.hpra.ie) By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Metopirone**

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

Do not use this medicine after the expiry date which is stated on the bottle and on the carton after EXP. The expiry date refers to the last day of that month. Use within two months of opening.

Keep the bottle tightly closed in order to protect from moisture. Store below 25°C

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

## **6. Contents of the pack and other information**

### **What Metopirone contains**

- The active substance is metyrapone. Each capsule contains 250 mg metyrapone.
- The other ingredients are: Ethylvanillin, gelatin, glycerol, macrogol 400, macrogol 4000, P-methoxy acetophenone, sodium ethyl parahydroxybenzoate (E215), Sodium propyl parahydroxybenzoate (E217), titanium dioxide (E171) and purified water. The printing ink (red) on the capsules contains: carminic acid (E120), aluminium chloride hexahydrate, sodium hydroxide, hypromellose and propylene glycol.

### **What Metopirone looks like and contents of the pack**

A white to yellowish-white, oblong, opaque, soft gelatin capsule imprinted in red ink with “M01”

and having faintly yellowish viscous to jelly-like contents. Capsule size: length 18.5 mm, diameter 7.5 mm. Each plastic bottle contains 50 capsules.

**Marketing Authorisation Holder**

Esteve Pharmaceuticals S.A.  
Passeig de la Zona Franca 109 Planta 4  
08038 Barcelona  
Spain  
+ 34 93 446 60 00

**Manufacturer**

DELPHARM LILLE S.A.S  
Parc d'activités Roubaix-Est 22 Rue de Toufflers CS 5007059452 LYS LEZ  
LANNOY  
France

**This medicinal product is authorised in the Member States of the European Economic Area under the following names:**

Ireland, Bulgaria, Croatia, Czech Republic, Greece, Latvia, Romania, Denmark, Finland, the Netherlands, Portugal, Poland, Spain, Sweden: Metopirone  
Slovakia: METOPIRONE  
Slovenia, Austria, Norway:  
MetycorFrance: Metyrapone  
Esteve  
Germany: Metopiron  
Italy, Estonia, Hungary, Lithuania: Cormeto

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