

ABIRATERONE ACETATE[®] NEAPOLIS

Read 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 applies to any side effect that is not mentioned in this leaflet. See section 4.

What is in this leaflet ? :

1. What is ABIRATERONE acetate NEAPOLIS and in which case is it used?
2. What you need to know before you take ABIRATERONE acetate NEAPOLIS?
3. How to take ABIRATERONE acetate NEAPOLIS?
4. Possible side effects
5. How to store ABIRATERONE acetate NEAPOLIS?
6. Content of the packaging and other information

1. What is ABIRATERONE acetate NEAPOLIS and in which case is it used ?

ABIRATERONE acetate NEAPOLIS contains a medicine called abiraterone acetate. ABIRATERONE acetate NEAPOLIS is indicated in combination with prednisone or prednisolone for the treatment of metastatic castration-resistant prostate cancer in adult males whose disease has progressed during or following chemotherapy with docetaxel.

2. What you need to know before you take ABIRATERONE acetate NEAPOLIS ?

Never take ABIRATERONE acetate NEAPOLIS :

- If you are allergic to abiraterone acetate or any of the other components contained in this medicine (listed in section 6).
- If you are a woman, especially if you are pregnant. ABIRATERONE acetate NEAPOLIS should only be used in male patients.
- If you have severe liver damage.

Do not take this medicine if any of the above applies to you. If in doubt, talk to your doctor or pharmacist before taking this medicine.

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine :

- If you have liver problems
- If you have been told that you have high blood pressure or heart failure or low blood potassium levels (low blood potassium levels may increase the risk of heart rhythm disturbances)
- If you have had any other heart or blood vessel problems
- If you have a fast or irregular heartbeat
- If you are short of breath
- If you have gained weight quickly
- If you have swelling of the feet, ankles or legs
- If you have taken a medicine called ketoconazole as treatment for prostate cancer
- About the need to take this medicine with prednisone or prednisolone
- About the possible effects on your bones
- If you have high blood sugar (blood sugar levels)

Tell your doctor if you have been told you have heart or vascular disease, including heart rhythm disturbances (arrhythmia), or if you are receiving medicines to treat these conditions.

Tell your doctor if you experience yellowing of the skin or eyes, darker urine, severe nausea or vomiting, as these could be signs or symptoms of liver problems. Rarely, liver failure (called acute hepatic failure) can be fatal.

A reduction in red blood cells, decreased sexual desire (libido), muscle weakness and / or muscle pain may appear.

If you are not sure whether any of these applies to you, talk to your doctor or pharmacist before taking this medicine.

Monitoring of blood parameters

ABIRATERONE acetate NEAPOLIS can affect your liver, although you may not have symptoms. While you are taking this medicine your doctor will check your blood tests periodically to check for any effects on your liver.

ABIRATERONE ACETATE 250mg

Tablet

Children and adolescents

This medicine should not be used in children and adolescents. If ABIRATERONE acetate NEAPOLIS is accidentally swallowed by a child or adolescent, go to hospital immediately and take the leaflet with you to show it to the emergency doctor.

Other medicines and ABIRATERONE acetate NEAPOLIS

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

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is important because ABIRATERONE acetate NEAPOLIS may increase the effects of a number of medicines, including heart medicines, tranquilizers, herbal medicines (eg St. John's Wort) and others. Your doctor may want to change the dose of these medicines. In addition, some medicines may increase or decrease the effects of ABIRATERONE acetate NEAPOLIS. This may cause side effects or cause ABIRATERONE acetate NEAPOLIS to not work as well as it should.

Androgen suppression therapy may increase the risk of heart rhythm disturbances. Tell your doctor if you are taking any medicines

- Used to treat heart rhythm disturbances (eg quinidine, procainamide, amiodarone and sotalol) ;

- Known to increase the risk of heart rhythm disturbances [for example methadone (used as a pain reliever and in detoxification from opioid addiction), moxifloxacin (an antibiotic), antipsychotics (used for severe mental illness)].

Tell your doctor if you are taking any of the medicines mentioned above.

ABIRATERONE ACETATE NEAPOLIS with food

- This medicine must not be taken with food (see section 3 : « Taking the medicine »).
- Taking ABIRATERONE acetate NEAPOLIS with food may cause side effects.

Pregnancy and breastfeeding

ABIRATERONE acetate NEAPOLIS should not be used in women.

- **This medicine can cause birth defects in an unborn child if taken by pregnant women.**

- **Women who are or may be pregnant should wear gloves if they have to touch or handle ABIRATERONE acetate NEAPOLIS.**

- **If you have sex with a woman who could become pregnant, use a condom and another effective method of birth control. If you have sex with a pregnant woman, use a condom to protect the unborn child.**

Driving and using machines

This medicine is unlikely to affect your ability to drive a vehicle and use certain tools or machines.

ABIRATERONE acetate NEAPOLIS contains lactose and sodium

- ABIRATERONE acetate NEAPOLIS contains lactose (a type of sugar). If you have been told by your doctor that you have an intolerance to certain sugars, contact your doctor before taking this medicine.

- This medicine contains sodium. This should be taken into account in patients controlling their dietary sodium intake.

3. How to take ABIRATERONE acetate NEAPOLIS?

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if in doubt.

How much to take

The recommended dose is 1000 mg (four tablets) once a day.

Taking the medicine

- Take this medicine by mouth.

- **Do not take ABIRATERONE acetate NEAPOLIS with food.**

- **Take ABIRATERONE acetate NEAPOLIS at least two hours after eating and do not eat anything for at least one hour after taking ABIRATERONE acetate NEAPOLIS** (see section 2 : « ABIRATERONE with food »).

- Swallow the tablets whole with water.

- Do not break the tablets.

- ABIRATERONE acetate NEAPOLIS is taken with a medicine called prednisone or prednisolone. Take prednisone or prednisolone exactly as your doctor has told you.

- You should take prednisone or prednisolone every day while you are taking

ABIRATERONE ACETATE[®] NEAPOLIS

ABIRATERONE acetate NEAPOLIS.

- The dose of prednisone or prednisolone you are taking may need to be changed if a medical emergency occurs. Your doctor will tell you if you need to change the dose of prednisone or prednisolone you are taking. Do not stop taking prednisone or prednisolone unless your doctor tells you.

Your doctor may also prescribe other medicines during treatment with ABIRATERONE acetate NEAPOLIS and prednisone or prednisolone.

If you have taken more ABIRATERONE acetate NEAPOLIS than you should

If you have taken more than you should, tell your doctor immediately or go to hospital immediately.

If you forget to take ABIRATERONE acetate NEAPOLIS

- If you forget to take ABIRATERONE acetate NEAPOLIS or prednisone or prednisolone, take your usual dose the next day.

- If you forget to take ABIRATERONE acetate NEAPOLIS or prednisone or prednisolone for more than one day, contact your doctor immediately.

If you stop taking ABIRATERONE acetate NEAPOLIS

Do not stop taking ABIRATERONE ACETATE NEAPOLIS or prednisone or prednisolone, unless your doctor has told you.

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

4. Possible side effects ?

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

Stop taking ABIRATERONE acetate NEAPOLIS and see your doctor immediately if you experience any of the following effects :

- Muscle weakness, muscle twitching or strong heartbeat (palpitations). These can be a sign of low potassium in your blood.

Other side effects include :

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

Water retention in your legs or feet, low blood potassium, high blood pressure, urinary tract infection, diarrhea.

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

High levels of fat in your blood, increased liver function test results, chest pain, irregular heartbeat (atrial fibrillation), heart failure, rapid heartbeat, severe infections called sepsis, broken bones, indigestion, blood in the urine, skin rash.

Uncommon (may affect up to 1 in 100 people) : Adrenal gland disorders (related to an imbalance in salt and water amounts), abnormal heart rhythm (arrhythmia), muscle weakness and / or muscle pain.

Rare (may affect up to 1 in 1,000 people) : Irritation of the lung (also called allergic alveolitis). Impaired liver function (also called acute liver failure).

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

Heart attack, changes in ECG - electrocardiogram (prolongation of the QT interval).

Bone loss can appear among men treated for prostate cancer. ABIRATERONE acetate NEAPOLIS in combination with prednisone or prednisolone may increase bone loss.

Reporting side effects

If you get any side effects talk to your doctor or pharmacist. This also applies to any side effects which are not mentioned in this leaflet. You can also report side effects directly via the national reporting system.

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

5. How to store ABIRATERONE acetate NEAPOLIS

- Store this medication at a temperature not exceeding 30 ° C in the original outer packaging.

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

ABIRATERONE ACETATE 250mg

Tablet

anything for at least one hour after taking ABIRATERONE acetate NEAPOLIS.

- Women who are pregnant or may be pregnant should not handle ABIRATERONE acetate NEAPOLIS without gloves.

- Do not use this medicine after the expiry date which is stated on the box and blister.

The expiry date refers to the last day of that month.

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

6. Content of the packaging and other information

What ABIRATERONE acetate NEAPOLIS 250mg contains

- The active substance is abiraterone acetate.

Each tablet contains 250 mg of abiraterone acetate.

- The other components :

microcrystalline cellulose, croscarmellose sodium, lactose, magnesium stearate, povidone, colloidal silica dioxide, sodium lauryl sulfate, sodium carboxymethyl starch

Excipients with known effects : Lactose, sodium

What does ABIRATERONE acetate NEAPOLIS look like and content of the outer packaging

ABIRATERONE ACETATE NEAPOLIS 250 mg :

Box of 120 oval-shaped tablets in aluminum / aluminum blisters.

Supply and prescription condition : Liste 1

M. A. N° :

ABIRATERONE acetate NEAPOLIS 250mg, tablet box of 120 :

Marketing Authorisation Holder and Manufacturer :

NEAPOLIS PHARMA

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11/2019

THIS IS A MEDICINE

- A medicine is not like other consumer goods.
- A medication is a product that affects your health and its consumption without compliance to the prescription exposes you to danger.
- You should strictly follow your doctor's prescription and directions for use, as well as the advice of your pharmacist.
- Your doctor and pharmacist are familiar with the medication, its indications and contraindications.
- Do not stop treatment on your own during the prescribed period.
- Do not resume, do not increase doses without consulting your doctor.

KEEP MEDICINES OUT OF THE REACH OF CHILDREN



NEAPOLIS
PHARMA