PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S2

RUCINTIX (capsules)

Fluconazole

Each RUCINTIX capsule contains sugar (lactose monohydrate 146,25 mg).

Read all of this leaflet carefully because it contains important information for you

RUCINTIX is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use RUCINTIX carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share RUCINTIX with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if the infection persists, or your symptoms worsen or do not improve.

What is in this leaflet

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

1. What RUCINTIX is and what it is used for

RUCINTIX contains fluconazole which is an antifungal agent. RUCINTIX 150 mg as a single dose is used to treat the following fungal infections in adults:

- Vaginal candidiasis (thrush), recurrent.
- Candidial balanitis (pain and inflammation (swelling and irritation) of the glans (head) of the penis) associated with vaginal candidiasis (thrush).

2. What you need to know before you take RUCINTIX

Do not take RUCINTIX if:

- You are hypersensitive (allergic) to fluconazole, to other medicines you have taken to treat fungal infections or any of the other ingredients of RUCINTIX (listed in section 6).
- You are taking antihistamines called terfenadine or astemizole.
- You are taking a medicine called cisapride to increase your bowel movements.
- if you are taking pimozide used for treating mental illness.
- if you are taking quinidine used for treating heart arrhythmia.
- if you are taking erythromycin an antibiotic for treating infections.
- You are pregnant or breastfeeding.
- You should not take multiple doses if you have a serious kidney problem.

Warnings and precautions:

Take special care with RUCINTIX:

Before taking this medication, tell your doctor if:

- You have kidney problems.
- You suffer from liver problems or start developing liver problems while taking this medicine. If you develop the following symptoms, you should speak to your doctor, as they may be signs of serious liver problems: feeling tired all the time, loss of appetite and weight loss (anorexia), feeling nauseous all the time, vomiting and jaundice (yellowing of the white of the eyes and skin).
- You are HIV positive.

- You have been diagnosed with any malignancies (cancer).
- You suffer from heart disease, including heart rhythm problems.
- You have abnormal levels of potassium in your blood (seen in blood tests).
- You develop severe skin reactions (itching, reddening of the skin or difficulty breathing).
- You develop signs of 'adrenal insufficiency' where the adrenal glands do not produce adequate amounts of certain steroid hormones such as cortisol, which may present with the following symptoms: chronic, or long lasting fatigue, muscle weakness, loss of appetite, weight loss, abdominal pain.
- If you have ever developed a severe skin rash or skin peeling, blistering of the skin, swelling, dry skin, abnormal odour, flaking and/or mouth sores after taking RUCINTIX.

Serious skin reactions including Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) have been reported in association with fluconazole treatment. Stop taking RUCINTIX and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Other medicines and RUCINTIX:

Always tell your health care provider if you are taking any other medicine–(this includes all complementary or traditional medicines).

Please advise your doctor or health care provider if you are using any of the following products as these should not be taken with RUCINTIX (see section "Do not take RUCINTIX if"):

- Cisapride a medicine used to increase bowel movements.
- Terfenadine and astemizole, antihistamines for treating allergies.
- Pimozide, used for treating mental illness.
- Quinidine, used for treating heart arrhythmia.
- Erythromycin, an antibiotic for treating infections.

The use of the following medicine together with RUCINTIX cannot be recommended and should be avoided:

- Halofantrine (used for treating malaria).

The use of the following medicine together with RUCINTIX should be used with caution:

- Amiodarone (used for treating uneven heartbeats ‘arrhythmias’).

RUCINTIX may interact with the following medicines. Make sure your doctor knows if you are taking any of these medicines as a dose adjustment or monitoring may be required to check that the medicines are still having the desired effect:

- Blood thinning agents to prevent blood clots e.g. warfarin or similar medicines.
- Medicines against epilepsy e.g. phenytoin, carbamazepine.
- Oral antidiabetic medicines such as chlorpropamide, glibenclamide, glipizide or tolbutamide.
- Theophylline, a medicine used to control asthma.
- Antiretroviral medicines e.g. zidovudine, saquinavir, nevirapine.
- Ciclosporin, everolimus, sirolimus and tacrolimus, immunosuppressants used after organ transplants to prevent rejection.
- Anti-anxiety medicines called benzodiazepines (e.g. midazolam, triazolam).
- Anti-TB medicine called rifabutin (RUCINTIX may also interact with the anti-TB medicine rifampicin by decreasing the blood level of this medicine which could lead to ineffectiveness of this medicine).
- The diuretic (medicine that increases urination), hydrochlorothiazide increases the blood levels of RUCINTIX.
- Abrocitinib (used to treat atopic dermatitis, also known as atopic eczema).
- Alfentanil, fentanyl (used as anaesthetic).
- Amitriptyline, nortriptyline (used as anti-depressant).
- Amphotericin B, voriconazole (anti-fungals).

- Calcium channel blockers e.g. Nifedipine, isradipine, amlodipine, verapamil, felodipine and the angiotensin II-receptor blocker losartan (high blood pressure medication).
- Celecoxib, flurbiprofen, naproxen, ibuprofen, lornoxicam, meloxicam, diclofenac (Non-Steroidal Anti-Inflammatory Drugs (NSAID)).
- Cyclophosphamide, vinca alkaloids (vincristine, vinblastine or similar medicines) used for treating cancer.
- Statins (atorvastatin, simvastatin and fluvastatin or similar medicines) used for reducing high blood cholesterol levels.
- Ibrutinib (used for treating blood cancer).
- Ivacaftor (used for treating cystic fibrosis).
- Olaparib (used for treating ovarian cancer).
- Lurasidone (used to treat schizophrenia).
- Methadone (used for pain).
- Prednisone (steroid).
- Tofacitinib (used for treating rheumatoid arthritis).
- Tolvaptan used to treat hyponatremia (low levels of sodium in your blood) or to slow kidney function decline.
- Vitamin A (nutritional supplement).
- Oral contraceptives.

RUCINTIX with food or drink:

You can take this capsule before or after meals, the presence of food will not influence the absorption of the medicine. Do not chew, crack or open the capsule and swallow it whole.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

RUCINTIX should not be used during pregnancy or by women who plan to become pregnant.

An effective form of birth control should be used during treatment with this product. Check with your doctor immediately if you think you have become pregnant while taking this medicine.

RUCINTIX should not be used during breastfeeding.

Driving and using machines:

RUCINTIX should not affect your ability to drive or use machinery, but you should refrain from driving or using machinery until you know how this medicine affects you as it may cause nausea, dizziness, headache or seizures (fits).

RUCINTIX contains lactose:

RUCINTIX contains lactose monohydrate. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take RUCINTIX.

RUCINTIX contain lactose monohydrate which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take RUCINTIX

Do not share medicines prescribed for you with any other person.

Always take RUCINTIX exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The usual does is:

Vaginal candidiasis (thrush), recurrent:

Adults: 150 mg administered as a single dose.

If the infection does not improve then you should consult a medical practitioner.

Candida balanitis:

Adults: 150 mg administered as a single dose.

If the infection does not improve then you should consult a medical practitioner.

The capsules should be swallowed whole with a glass of water.

If you take more RUCINTIX than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take this leaflet and any remaining capsules with you, so that the doctor knows what the person has taken.

If you forget to take RUCINTIX:

Take the missed dose as soon as possible. However, if it is almost time for you next dose, continue to take the next capsule at the usual time. Do not take a double dose.

If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

If you stop taking RUCINTIX:

It is important to keep taking your medicine for as long as your doctor prescribes them. Do not stop taking your medicine without consulting your doctor first.

4. Possible side effects

RUCINTIX can have side effects.

Not all side effects reported for RUCINTIX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking RUCINTIX, please consult your health care provider for advice.

If any of the following happens, stop taking RUCINTIX and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Sudden wheezing, difficulty in breathing or tightness in the chest skin rash, hives or itching skin, reddening of the skin
- Fever and chills
- Swelling of face, eyelids or lips, arms, hands, lower legs or feet
- Difficulty in swallowing
- Severe skin reactions that causes blistering, peeling or loosening of skin (this can affect the mouth and tongue)
- Hypersensitivity reaction with widespread skin rash, fever, swollen glands, enlarged lymph nodes, increase in a type of white blood cell (eosinophilia) and inflammation of internal organs (liver, lungs, heart, kidneys and large intestine) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)) or drug hypersensitivity syndrome.
- RUCINTIX may affect your liver leading to liver damage and failure. The signs of liver problems include:
    - tiredness
    - loss of appetite
    - vomiting
    - yellowing of the skin or the whites of the eyes (jaundice)

These are all very serious side effects. If you have them, you may have had a serious reaction to RUCINTIX. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Nausea
- Headache

- Vomiting
- Stomach pain
- Diarrhoea
- Flatulence (wind)
- Increases in blood tests of liver function
- Rash

Less frequent side effects:

- Reduction in red blood cells which can make skin pale and cause weakness or breathlessness
- Lower than normal white blood cells that help defend against infections and blood cells that help to stop bleeding
- Red or purple discoloration of the skin which may be caused by low platelet count, other blood cell changes
- Decreased appetite
- Low blood potassium
- Blood chemistry changes (high blood levels of cholesterol, fats)
- Dizziness
- Fits
- Sensation of tingling, pricking or numbness
- Unusual or unpleasant taste in mouth, with changes in sense of taste
- Shaking
- Nervousness
- Restlessness
- Sleeping problems
- Feeling drowsy
- Blurred vision
- Sensation of your head spinning (vertigo)

- Abnormal electrocardiogram (ECG) (the ability of your heart to conduct electricity)
- Change in heart rate or rhythm
- Constipation
- Difficult digestion
- Dry mouth
- Thirst
- Temporary hair loss
- Increased sweating
- Muscle pain and overactivity
- Excessive passing of urine
- Female sexual dysfunction, bleeding between menstrual cycles, excessive menstrual bleeding, vaginal discharge
- Unusual tiredness or weakness
- General feeling of being unwell
- Fever

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of RUCINTIX. Suspected side effects can also be reported directly to the Holder of the Certificate of Registration (HCR) via: https://pvi1j.solutions.iqvia.com or patient.safety.sac@sandoz.com.

5. How to store RUCINTIX

Store at or below 25 ºC.

Do not remove the blisters from the outer container until required for use.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not use the capsules after the expiry date printed on the carton or label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What RUCINTIX contains:

Each RUCINTIX capsule contains 150 mg fluconazole.

Inactive ingredients of RUCINTIX:

Anhydrous colloidal silica, hard gelatin capsule**, lactose monohydrate, magnesium stearate, maize starch, sodium lauryl sulfate

***Hard Gelatin capsule** composed of:* Black iron oxide (E 172), gelatin, indigo carmine FD&C Blue 2, propylene glycol (E 1520), shellac, titanium dioxide.

What RUCINTIX looks like and contents of the pack:

RUCINTIX: Hard gelatin capsules, snap-fit closure, white cap / white body, with the imprint FC150, containing a white odourless powder.

RUCINTIX: White, opaque PVC/Aluminium blister~~s~~ strip~~s~~ containing 1 capsule.

Holder of Certificate of Registration

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2090

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RUCINTIX: 36/20.2.2/0262

Access to the corresponding Professional Information

Not applicable.

[1]Company Reg. No.: 1990/001979/07