V1.1 (22.06.2021)

Patient information leaflet

SCHEDULING STATUS **S4**

TACTUS® 10 mg (tablets)

Ezetimibe

Contains sugar (67,5 mg lactose monohydrate)

Read all of this leaflet carefully before you start taking TACTUS.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- TACTUS has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What TACTUS is and what it is used for

TACTUS is a medicine used to lower levels of total cholesterol, "bad" cholesterol (LDL cholesterol) and fatty substances called triglycerides in the blood. Additionally, TACTUS raises levels of "good" cholesterol (HDL cholesterol). TACTUS works by reducing the cholesterol absorbed in your digestive tract.

TACTUS is used for patients who cannot control their cholesterol levels by diet alone. You should however stay on a cholesterol-lowering diet while taking TACTUS.

TACTUS adds to the cholesterol-lowering effect of statins, a group of medicines that reduce

the cholesterol your body makes by itself.

2. What you need to know before you take TACTUS

Do not take TACTUS:

- If you are hypersensitive (allergic) to ezetimibe or any of the other ingredients of TACTUS (see What TACTUS contains).
- If you are pregnant or breastfeeding (see Pregnancy, breastfeeding and fertility).
- If you have moderate or severe liver problems.
- TACTUS co-administered with a statin is contraindicated in patients with active liver disease or unexplained persistent elevations in serum transaminases.

TACTUS is not recommended in children under the age of 10 years.

Warnings and precautions

Take special care with TACTUS:

- If you experience any unexplained muscle pain, tenderness or muscle weakness. Contact your doctor immediately.
- If you are already taking other medicines to lower your cholesterol levels in the blood.
- If you are taking warfarin tablets used to prevent blood clots or any other anti-clotting medicine.

Your doctor should do a blood test before you start taking TACTUS with a statin. This is to check how well your liver is working.

Your doctor may also want you to do blood tests to check how well your liver is working after you start taking TACTUS with a statin.

Do not give TACTUS to children below 10 years, as safety and efficacy have not been established.

Other medicines and TACTUS

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

Tell your doctor or pharmacist if you are currently using:

- cholestyramine (used to lower cholesterol), because it affects the way **TACTUS** works;
- fibrates (medicines used to lower cholesterol);
- ciclosporin (used to prevent organ rejection after a transplant);
- medicines to prevent blood clots, such as warfarin (anticoagulants).

TACTUS with food, drink and alcohol

See section 3.

Pregnancy, breastfeeding and fertility

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 TACTUS.

Do not take TACTUS if you are pregnant or breastfeeding.

Driving and using machines

TACTUS can cause side effects, such as dizziness. Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how TACTUS affects you.

TACTUS contains lactose monohydrate

Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take TACTUS.
TACTUS contains lactose monohydrate, which may have an effect on the glycaemic control of patients with diabetes mellitus.

3. How to take TACTUS

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

Always take TACTUS exactly as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Before starting TACTUS, you should be on a diet to lower your cholesterol. You

should stay on this diet whilst taking TACTUS.

Adults and children (10 years of age and older):

The usual dose is one TACTUS tablet once a day.

Take TACTUS at any time of the day. You can take TACTUS with or without food.

If your doctor has prescribed TACTUS along with any other medicine containing bile acid sequestrant, you should take TACTUS at least 2 hours before or 4 hours after taking the bile acid sequestrant.

Your doctor will tell you how long your treatment with TACTUS will last. Do not stop treatment early.

If you have the impression that the effect of TACTUS is too strong or too weak, tell your doctor or pharmacist.

If you take more TACTUS than you should

In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Take this leaflet and the rest of the remaining TACTUS with you so the doctor will know what you have taken.

If you forget to take TACTUS

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

TACTUS can have side effects.

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

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

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash, hives or itching;
- fainting.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- chest pain;
- bleeding or bruising more easily than normal;
- myopathy (unexplained muscle pain, tenderness or weakness, stiffness or cramping);
- inflammation of pancreas (nausea, vomiting, fever, pain of your stomach area that radiates to your back, increased heart rate);
- rhabdomyolysis (temporary paralysis or weakness of muscles);
- yellowing of your skin and eyes, dark urine, and tiredness which may be symptoms of liver problems;

- inflammation of your gallbladder or gallstones (persistent pain in the abdominal area, fever, nausea and vomiting, sweating, loss of appetite).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following frequent side effects:

- viral infections, infections of the sinuses (runny nose, nasal congestion);
- upper respiratory tract infection (sneezing, runny nose, scratchy or sore throat, fever);
- cough;
- abdominal pain, diarrhoea, flatulence (wind), constipation, nausea (feeling sick);
- joint pain, back pain, muscle pain;
- headache, dizziness;
- feeling tired;
- elevations in liver function when blood tests are done (increased alanine transaminases (ALT) and/or aspartate transaminase (AST)).

Less frequent side effects:

- decreased appetite;
- hot flush;
- high blood pressure;
- indigestion, dry mouth, heartburn;
- muscle spasms, neck pain, hand or foot pain;
- increased blood creatinine phosphokinase or gamma-glutamyl transferase levels when blood tests are done;
- tingling or numbness of your hands and feet (pins and needles);
- weakness or lack of energy.

Frequency unknown side effects:

- feeling depressed;
- shortness of breath (dyspnoea);
- raised red rash, sometimes with target-shaped lesions (erythema multiforme).

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 or pharmacist. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: http://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of TACTUS. Suspected adverse reactions can also be reported directly to the HCR (Holder of Certificate of Registration) via Patientsafety.sacg@novartis.com.

5. How to store TACTUS

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

This medicine does not require any special storage conditions.

- Store in the original package in order to protect from moisture.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets). These measures will help protect the environment.
- Do not use this medicine after the expiry date, which is stated on the blister, carton or bottle after EXP. The expiry date refers to the last day of that month.

6. Contents of the pack and other information

What TACTUS contains

Each tablet contains 10 mg ezetimibe.

The other ingredients are:

Lactose monohydrate

Sodium lauryl sulfate

Croscarmellose sodium

Hypromellose

Cellulose, microcrystalline

Magnesium stearate

What TACTUS looks like and contents of the pack

Tablet.

TACTUS 10 mg tablets are white to almost white, oval tablets with debossing “10” on one side and “EZT” on the other side.

TACTUS 10 mg Tablets are packed into Al/Al blisters or Aqua Ba blisters in packs of 30. Not all pack sizes may be marketed.

Holder of certificate of registration

Sandoz SA (Pty) Ltd[1]

Waterfall 5-Ir

Magwa Crescent West

Waterfall City

Jukskei View

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Not applicable

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