PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

DEZZOLIP 10 (Atorvastatin) film-coated tablets

DEZZOLIP 20 (Atorvastatin) film-coated tablets

DEZZOLIP 40 (Atorvastatin) film-coated tablets

DEZZOLIP 80 (Atorvastatin) film-coated tablets

DEZZOLIP 10 contains sugar (mannitol 70,97 mg/tablet)

DEZZOLIP 20 contains sugar (mannitol 141,94 mg/tablet)

DEZZOLIP 40 contains sugar (mannitol 283,88 mg/tablet)

DEZZOLIP 80 contains sugar (mannitol 567,76 mg/tablet)

Read all of this leaflet carefully before you start taking DEZZOLIP

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- DEZZOLIP 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

PROPOSED AMENDED PATIENT INFORMATION LEAFLET

1. What DEZZOLIP is and what it is used for

DEZZOLIP belongs to a group of medicines known as statins, which are lipid (fat) regulating medicines.

DEZZOLIP is used to lower lipids known as cholesterol and triglycerides in the blood when a low fat diet and life style changes on their own have failed. If you are at an increased risk of heart disease, DEZZOLIP can also be used to reduce such risk even if your cholesterol levels are normal. You should maintain a standard cholesterol lowering diet during treatment.

2. What you need to know before you take DEZZOLIP

Do not take DEZZOLIP:

- if you are hypersensitive (allergic) to atorvastatin or any of the other ingredients of DEZZOLIP,
- if you have or had a disease which affects the liver,
- if you have had any unexplained abnormal blood tests for liver function,
- if you are taking medication for tuberculosis, high blood pressure, heart pain or any other heart condition,
- if you take grapefruit juice,
- if you are a women of child bearing age and not using reliable contraception,
- if you are pregnant or planning to become pregnant,

if you are breastfeeding.

Warnings and special precautions

Tell your doctor or healthcare professional before being given DEZZOLIP:

- if you have had a previous stroke with bleeding into the brain, or have small pockets of fluid in,

- if you have a history of liver disease,
- if you have a history of kidney disease,
- if you have a history of heart failure, heart attack or any other form of heart disease,
- if you have an under-active thyroid gland (hypothyroidism),
- if you have had repeated or unexplained muscle aches or pains, a personal history or family history of muscle problems,
- if you have had previous muscular problems during treatment with other lipid-lowering medicines (e.g. other '-statin' or '-fibrate' medicines),
- if you regularly drink a large amount of alcohol,
- if you are elderly (older than 70 years).

If any of these apply to you, your doctor will need to carry out a blood test before and possibly during your DEZZOLIP treatment to predict your risk of muscle related side effects.

Children and Adolescents: For use in children, take DEZZOLIP only if you are between the ages of 10 – 17 years. Do not take more than 20 mg per day.

Talk to your doctor before taking DEZZOLIP if you have diabetes. There have been reports of an increase in glycosylated haemoglobin (a situation where glucose becomes stuck to haemoglobin) and an increase in fasting blood sugar levels when taking DEZZOLIP. This could be a sign or indication that your diabetes is not well controlled.

Other medicines and DEZZOLIP:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

- medicines used to alter the way your immune system works, e.g. ciclosporin

- certain antibiotics or antifungal medicines, e.g. erythromycin, clarithromycin, telithromycin, ketoconazole, itraconazole, voriconazole, fluconazole, posaconazole, rifampicin, fusidic acid
- other medicines to regulate lipid levels, e.g. gemfibrozil, other fibrates, colestipol
- some calcium channel blockers used for angina or high blood pressure, e.g. amlodipine, diltiazem; medicines to regulate your heart rhythm e.g. digoxin, verapamil, amiodarone
- medicines used in the treatment of HIV e.g. ritonavir, lopinavir, atazanavir, indinavir, darunavir, etc.
- other medicines known to interact with DEZZOLIP include ezetimibe (which lowers cholesterol), warfarin (which reduces blood clotting), oral contraceptives, stiripentol (an anti-convulsant for epilepsy), cimetidine (used for heartburn and peptic ulcers), phenazone (a painkiller) and antacids (indigestion products containing aluminium or magnesium)
- medicines obtained without a prescription: St John's Wort.

Taking DEZZOLIP with food and drink:

Grapefruit juice

Do not take grapefruit juice because it can change the effects of DEZZOLIP.

Alcohol

Avoid drinking too much alcohol while taking DEZZOLIP.

Pregnancy and breastfeeding and fertility

If you are pregnant or breastfeeding while taking DEZZOLIP, please consult your doctor, pharmacist or other health care professional for advice.

Do not take DEZZOLIP if you are pregnant, or if you are planning to become pregnant.

Women of child-bearing age should use appropriate contraceptive measures during treatment with DEZZOLIP.

Do not take DEZZOLIP if you are breastfeeding.

Driving and using machinery

DEZZOLIP may cause dizziness, headache, blurred vision and visual disturbances. Do not use any tools or machines or drive if your ability is affected by DEZZOLIP.

3. How to take DEZZOLIP

Do not share medicines prescribed for you with any other person. Always take DEZZOLIP exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Before starting treatment, your doctor will place you on a low-cholesterol diet, which you should maintain also during therapy with DEZZOLIP.

1. The usual starting dose of DEZZOLIP is 10 mg once a day in adults and children aged 10 – 17 years old. This may be increased if necessary by your doctor until you are taking the amount you need. Your doctor will adapt the dose at intervals of 4 weeks or more. The maximum dose of DEZZOLIP is 80 mg once daily for adults and 20 mg once daily for children aged 10 – 17 years old.
2. Take tablets whole and swallow with a sufficient quantity of water, and take at any time of the day, with or without food. However, try to take your tablet at about the same time every day.
3. Your doctor will tell you how long your treatment with DEZZOLIP will last.
4. If you have the impression that the effect of DEZZOLIP is too strong or too weak, tell your doctor or pharmacist.

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If you take more DEZZOLIP than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take DEZZOLIP:

Try to take DEZZOLIP as prescribed. However, if you forget to take a dose, just take your next scheduled dose at the correct time. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

DEZZOLIP can have side effects.

Not all side effects reported for DEZZOLIP are included in this leaflet. Should your general health worsen while taking DEZZOLIP, please consult your doctor, pharmacist or other health care professional for advice.

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

- serious allergic reaction which causes swelling of the face, tongue and throat that can cause great difficulty in breathing,
- serious illness with severe peeling and swelling of the skin, blistering of the skin, mouth, eyes, genitals and fever. Skin rash with pink-red blotches especially on palms of hands or soles of feet which may blister,
- muscle weakness, tenderness or pain and particularly, if at the same time, you feel unwell or have a high temperature it may be caused by an abnormal muscle breakdown which can be life-threatening and lead to kidney problems,
- problems with unexpected or unusual bleeding or bruising, this may be suggestive of a liver problem. You should consult your doctor as soon as possible.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to DEZZOLIP. 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,
- swelling below the skin surface that may affect any part of the body including the eyes, hands, feet, genitals and mouth,
- difficulty breathing,
- redness and swelling of the passages in the nose, pain in the throat, nose bleeding, joint pain, muscle pain and back pain.

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

Tell your doctor if you notice any of the following:

Frequent:

- nasopharingitis (sore, inflamed throat),
  reductions of sensation to pain or touch, dizziness, headache,
- nausea (feeling sick), diarrhoea, abdominal pain or stomach cramps, indigestion, constipation, flatulence or wind,
- itching and rash,
- muscle pain, pain in a joint or joints, back pain,
- weakness or lack of energy.

Less frequent:

- if your blood takes longer to clot, you may have a lower than normal number of white blood cells and platelets in the blood,

- low or high blood sugar (ask your doctor how often you should have your blood tested and what tests you need to have done), weight loss, weight gain,
- nightmares, difficulty in sleeping, partial or total loss of memory, forgetfulness, confusion, numbness or tingling in the fingers and toes, change in sense of taste,
- blurred vision,
- ringing in the ears and/or head, hearing loss,
- nausea and vomiting, belching, upper and lower stomach pain, pancreatitis (inflammation of the pancreas leading to stomach pain),
- inflammation of the liver (you may feel sick, tired, have dark urine, unusually light coloured stools, yellowing of the skin and whites of the eyes), liver failure (you may feel sick, tired, have diarrhoea and a swollen stomach),
- loss of hair, hives, skin rash, itching,
- inflammation of the muscle tissue, muscle weakness, muscle cramps, neck pain, tendon injury,
- gynaecomastia (breast enlargement in men and women),
- impotence (inability to have an erection),
- weakness, swelling especially in the ankles (oedema), tiredness, raised temperature.

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.

Report all side effects to Unicorn Pharmaceuticals (Pty) Ltd at enquiries@unicornpharma.co.za

By reporting side effects, you can help provide more information on the safety of DEZZOLIP.

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5. How to store DEZZOLIP

- Store all medicines out of the reach of children.
- Store at or below 25 °C.
- Protect from moisture.
- Keep the blisters in the outer carton until required for use.
- Do not use after the expiry date stated on the carton.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

WHAT DEZZOLIP contains

The active substance in DEZZOLIP is atorvastatin.

DEZZOLIP 10**:** Each film-coated tablet contains atorvastatin calcium trihydrate equivalent to 10 mg atorvastatin.

DEZZOLIP 20: Each film-coated tablet contains atorvastatin calcium trihydrate equivalent to 20 mg atorvastatin.

DEZZOLIP 40: Each film-coated tablet contains atorvastatin calcium trihydrate equivalent to 40 mg atorvastatin.

DEZZOLIP 80: Each film-coated tablet contains atorvastatin calcium trihydrate equivalent to 80 mg atorvastatin.

The other ingredients are anhydrous sodium carbonate, butylated hydroxyanisole, colloidal anhydrous silica, croscarmellose sodium, mannitol, microcrystalline cellulose, septifilm LP 010 (hypromellose, microcrystalline cellulose and stearic acid) and sodium lauryl sulphate.

What DEZZOLIP looks like and contents of the pack

DEZZOLIP 10: White coloured, oval shaped, biconvex film coated tablets with one side embossed “10” and other side plain.

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DEZZOLIP 20: White coloured, oval shaped, biconvex film coated tablets with one side embossed “20” and other side plain.

DEZZOLIP 40: White coloured, oval shaped, biconvex film coated tablets with one side embossed “40” and other side plain

DEZZOLIP 80: White coloured, oval shaped, biconvex film coated tablets with one side embossed “80” and other side plain.

Blisters: Alu-Alu blister composed of silver opaque Alu-Alu cold form laminate & silver opaque Aluminium foil containing 7 tablets or 10 tablets.

Cartons containing 28 tablets (4 x 7’s) or 30 tablets (3 x 10’s).

Holder of certificate of registration

Unicorn Pharmaceuticals (Pty) Ltd

Corner Searle & Pontac Streets

Cape Town

8000

enquires@unicornpharma.co.za

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