PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

FIDURSI 120 mg/2,4 ml concentrate for solution for infusion

FIDURSI 500 mg/10 ml concentrate for solution for infusion

Durvalumab

Sugar-free

Read all of this leaflet carefully before you are given

FIDURSI

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

What is in this leaflet

1. WHAT FIDURSI IS AND WHAT IT IS USED FOR:

The active substance is durvalumab.

FIDURSI is used to treat a type of lung cancer called non-small cell lung cancer (NSCLC). It is used when your NSCLC has spread within your lung and cannot be removed by surgery and has responded or stabilised after initial treatment with chemotherapy and radiotherapy.

FIDURSI is used in together with chemotherapy to treat a type of lung cancer called extensive-stage small cell lung cancer (ES-SCLC). It is used when your SCLC has spread within your lungs (or to other parts of the body) and has not previously been treated.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE FIDURSI

You should not be given FIDURSI:

- if you are hypersensitive (allergic) to durvalumab or any of the other ingredients of FIDURSI listed in section 6.

Warnings and precautions

Take special care with FIDURSI.

Tell your doctor or healthcare professional before being given the

injection if you:

- have immune system problems such as Crohn's disease, ulcerative colitis or lupus.
- have had an organ transplant.
- have lung or breathing problems.
- have liver problems.
- are pregnant or plan to become pregnant. FIDURSI can harm your unborn baby. If you are able to become pregnant, you should use an effective method of birth control during your treatment and for at least 3 months after the last dose of FIDURSI.
- are breastfeeding or plan to breastfeed. It is not known if FIDURSI passes into your breast milk. Do not breastfeed during treatment and for at least 3 months after the last dose of FIDURSI.

If any of the above apply to you (or you are not sure), talk to your doctor or healthcare professional before receiving FIDURSI.

If you have any of the following, tell your doctor immediately. Your doctor may give you other

medicines in order to prevent more severe complications and reduce your symptoms. Your doctor may withhold the next dose of FIDURSI or stop your treatment with FIDURSI:

- inflammation of the lungs: Signs and symptoms may include new or worsening cough, shortness of breath or chest pain.
- inflammation of the liver: Signs and symptoms may include nausea or vomiting, feeling less hungry, pain on the right side of stomach, yellowing of skin or whites of eyes, drowsiness, dark urine or bleeding or bruising more easily than normal.
- inflammation of the intestines: Signs and symptoms may include diarrhoea or more bowel movements than usual, black, tarry, sticky stools or stools with blood or mucous severe stomach pain or tenderness.
- inflammation of hormone glands (especially the thyroid, adrenals, pituitary and pancreas): Signs and symptoms may include headaches that will not go away or unusual headaches, extreme tiredness, weight gain or weight loss, dizziness or fainting, feeling more hungry or thirsty than usual, hair loss, feeling cold, constipation, changes to your voice, urinating more often than usual, nausea or vomiting, stomach area (abdomen) pain, changes in mood or behaviour, such as decreased sex drive, irritability or forgetfulness.
- inflammation of the kidneys: Signs and symptoms may include changes in the amount or colour of your urine, swelling in your ankles or loss of appetite.
- inflammation of the skin or mouth: Signs and symptoms may include rash, itching, skin blistering or ulcers in mouth or other mucous membranes.
- inflammation of the heart: Signs and symptoms may include chest pain, shortness of breath or irregular heartbeat.
- inflammation of muscles: Signs and symptoms may include severe muscle weakness, tiredness or pain, in one or more areas of your body.
- infusion related reactions: Signs and symptoms may include chills or shaking, itching or rash, flushing, shortness of breath or wheezing dizziness, fever, feeling like passing out, back or neck pain or facial swelling.

- *Human Immunodeficiency Virus (HIV):* FIDURSI has not been studied in patients with HIV

Children and adolescents:

FIDURSI has not been studied in children or adolescents. Do not give this medicine to children or adolescents aged less than 18 years.

Other medicines and FIDURSI:

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

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 this medicine.

If you are a woman who could become pregnant, you must use adequate birth control while you are being treated with FIDURSI and for at least 3 months after your last dose.

Do not breastfeed while taking FIDURSI and for at least 3 months after last dose.

It is not known if FIDURSI passes into your breast milk.

Driving and using machinery:

FIDURSI is unlikely to affect the ability to drive and use machines.

However, if you experience adverse reactions affecting your ability to concentrate and react, you should use caution when driving or operating machinery.

3. HOW TO USE FIDURSI

FIDURSI will be given to you in a hospital or clinic under the supervision of an experienced doctor.

The recommended dose of FIDURSI is 10 mg per kg of your body weight every 2 weeks or 1500 mg every 3 or 4 weeks.

Your doctor will give you FIDURSI through an infusion (drip) into your vein (IV) for about 60 minutes. Your

doctor will decide how many treatments you need.

How much FIDURSI will you be given:

The recommended dose is 10 mg of FIDURSI per kilogram of your body weight.

If you miss an appointment to get FIDURSI

Call your doctor or healthcare professional right away to reschedule your appointment. It is very important that you do not miss a dose of FIDURSI.

If you have any further questions about your treatment, ask your doctor.

4. POSSIBLE SIDE EFFECTS:

FIDURSI can have side effects.

Not all side effects reported for FIDURSI are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking FIDURSI, please consult your doctor, pharmacist or other healthcare professional for advice.

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

- inflammation of the lungs (pneumonitis)
- stomach pain
- fever
- lung infection (pneumonia)

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

Tell your doctor if you notice any of the following:

The following side effects have been frequently reported:

- cough
- diarrhoea
- stomach pain
- skin rash or itchiness

- fever
- swelling of the legs (peripheral oedema)
- upper respiratory tract infection

The following side effects have been reported less frequently:

- fungal infection in the mouth
- flu-like illness
- raised blood sugar levels (type 1 diabetes mellitus)
- hoarse voice (dysphonia)
- inflammation of the gut or intestine (colitis)
- night sweats

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 or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of FIDURSI.

5. HOW TO STORE FIDURSI:

Keep all medicines out of the reach and sight of children.

Store at 2 °C – 8 °C (in a refrigerator)

Do not freeze. Do not shake.

Store in the original package to protect from light.

Do not use this medicine after the expiry date which is stated on the carton and vial label. The expiry date refers to the last day of that month.

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION

FIDURSI 120 mg/2,4 ml:

2,4 ml of concentrate in a 10 ml Type 1 glass vial with an elastomeric stopper and a gray flip-off aluminum seal contains 120 mg durvalumab. Pack size of 1 vial.

FIDURSI 500 mg/10 ml:

10 ml of concentrate in a 10 ml Type 1 glass vial with an elastomeric stopper and a white flip-off aluminum seal contains 500 mg durvalumab. Pack size of 1 vial.

The other ingredients are L-histidine, L-histidine hydrochloride monohydrate, α,α-trehalose dihydrate and polysorbate 80.

What FIDURSI looks like and contents of the pack:

The solution in the vial is sterile, preservative-free, clear to opalescent, colourless to slightly yellow and free from visible particles.

Holder of certificate of registration

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REGISTRATION NUMBER(S):

FIDURSI 120 mg/2,4 ml: 54/30.1/0003.001

FIDURSI 500 mg/10 ml: 54/30.1/0004.002

Access to the corresponding Professional Information

AstraZeneca Logo