PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

AUBERIF™ 14 mg film-coated tablets

teriflunomide

Contains sugar (76 mg lactose monohydrate per tablet)

AUBERIF may cause serious side effects, including:

1. Liver problems: AUBERIF may cause serious liver problems that may lead to death. Your risk of liver problems may be higher if you take other medicines that also affect your liver.

   Your doctor should do blood tests to check your liver function:

   - within 6 months before you start taking AUBERIF
   - once a month for 6 months after you start taking AUBERIF.

   Tell your doctor right away if you have any of the following symptoms of liver problems:

   - nausea
   - vomiting
   - stomach pain
   - loss of appetite
   - tiredness
   - your skin or whites of your eyes turn yellow
   - dark urine.
2. Harm to your unborn baby: AUBERIF may cause harm to your unborn baby. Do not take AUBERIF if you are pregnant. Do not take AUBERIF unless you are using effective birth control.

   - If you are a female, you should have a pregnancy test before you start taking AUBERIF. Use effective birth control during your treatment with AUBERIF.

- After stopping AUBERIF, continue using effective birth control until you have blood tests to make sure your blood levels of AUBERIF are low enough. If you become pregnant while taking AUBERIF or within 2 years after you stop taking it, tell your doctor right away.
- **For men taking AUBERIF:** While taking AUBERIF you should use barrier contraception to prevent your partner from falling pregnant (see section 2 – *Use in males*).

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- AUBERIF 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 AUBERIF is and what it is used for
2. What you need to know before you take AUBERIF
3. How to take AUBERIF
4. Possible side effects
5. How to store AUBERIF
6. Contents of the pack and other information.

1. What AUBERIF is and what it is used for

AUBERIF contains the active substance teriflunomide which is an immunomodulatory agent and adjusts the immune system to limit its attack on the nervous system.

AUBERIF is used in adults to treat relapsing forms of multiple sclerosis (MS).

AUBERIF does not cure MS, but it helps to reduce the number of relapses and to slow down the progression of physical disabilities due to MS.

2. What you need to know before you take AUBERIF

Do not take AUBERIF

- If you are hypersensitive (allergic) to teriflunomide or leflunomide, or any of the other ingredients of AUBERIF (listed in section 6).
- If you have severe liver problems.
- If you are taking leflunomide (used for rheumatoid arthritis).
- If you are a woman who is pregnant or planning to become pregnant or if you are able to become pregnant and not using effective birth control methods.
- If you are breastfeeding.

Warnings and precautions

Tell your doctor or health care provider before taking AUBERIF:

- If you have liver problems. During the treatment your doctor will periodically request blood tests to monitor your liver function. If your test results indicate a problem with your liver, you may have to interrupt treatment with AUBERIF. If you notice yellowing of your skin or the whites of your eyes, abnormal darkening of your urine or unexplained nausea and vomiting, **tell your doctor immediately**. Your risk of liver problems may be higher if you take other medicines that also affect your liver (see section 4).
- If you have high blood pressure (hypertension) and whether it is controlled with medicines or not, AUBERIF can cause your blood pressure to increase. Therefore, your doctor will check your blood pressure before you start taking AUBERIF and regularly thereafter.
- If you suffer from a serious problem which affects your immune system.
- If you have an infection. Before you take AUBERIF, your doctor will make sure you have enough white blood cells and platelets in your blood. As AUBERIF decreases the number of white cells in the blood, this may affect your ability to fight the infection and the infection may

get worse. Your doctor may do blood tests to check your white blood cells if you think you have an infection.

- If you develop a serious infection while you are taking AUBERIF or have symptoms such as fever, or flu symptoms, call your doctor right away.
- If you plan to get vaccinated.
- If you have severe skin reactions or if you develop serious skin reactions or mouth ulcers during treatment (see section 4).
- If you have weakness, numbness and pain in the hands and feet.
- If you have or develop respiratory symptoms (e.g. coughing or difficulty breathing).
- If you are lactose intolerant.
- If you develop symptoms of severe skin reactions (skin rash, including flu-like symptoms, fever, swollen lymph nodes, peeling or blistering of your mouth, nose, eyes or genitals). These are serious reactions which may be fatal if not treated immediately (see section 4).

Children and adolescents

AUBERIF is not intended to be used in children and adolescents below 18 years old as it has not been studied in MS patients below 18 years old.

Other medicines and AUBERIF

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

Tell your doctor especially if you are taking any of the following medicines:

- leflunomide for rheumatoid arthritis. Leflunomide must not be taken with AUBERIF (see Do not take AUBERIF, above)
- ciclosporin and methotrexate and other medicines that affect the immune system (often called immunosuppressants or immunomodulators)
- rifampicin for tuberculosis

- carbamazepine, phenobarbital (phenobarbitone), phenytoin, antiepileptic medicines
- St John's wort, a herbal medicine for depression
- repaglinide, pioglitazone, rosiglitazone for diabetes
- paclitaxel, daunorubicin, doxorubicin, topotecan for treating cancer
- duloxetine for depression
- ethinylestradiol and levonorgestrel, used as oral contraceptives
- theophylline for asthma
- tizanidine, a muscle relaxant
- warfarin, an anticoagulant used to make the blood "thinner" in order to avoid blood clots (your dose of warfarin may need to be adjusted to avoid blood clots)
- cefaclor, penicillin, ciprofloxacin for infections
- indometacin, ketoprofen for pain or inflammation
- furosemide for heart disease
- cimetidine for reducing gastric acid
- zidovudine for HIV infection
- rosuvastatin, simvastatin, atorvastatin, pravastatin for high cholesterol
- sulfasalazine for inflammatory bowel disease or arthritis.

Pregnancy and breastfeeding

Do not take AUBERIF if you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby. Consult your doctor, pharmacist or health care provider for advice before taking AUBERIF.

Pregnancy

If you are pregnant or become pregnant while taking AUBERIF, the risk of having a baby with birth defects is increased. Women of childbearing potential must not take AUBERIF without using reliable contraceptive measures (see ***Contraception*** below).

Tell your doctor if you plan to become pregnant after stopping treatment with AUBERIF, as you need to ensure that most of this medicine has left your body before trying to become pregnant. The elimination of the active substance (teriflunomide) may take up to 2 years to occur naturally. The time can be reduced to a few weeks by taking certain medicines which speed up removal of AUBERIF from your body.
In either case it should be confirmed by a blood test that the active substance has been sufficiently removed from your body and you need confirmation from your doctor that the blood level of AUBERIF is low enough to allow you to become pregnant.

If you suspect that you are pregnant or become pregnant while taking AUBERIF or in the two years after you have stopped treatment, you must contact your doctor immediately for a pregnancy test. If the test confirms that you are pregnant, your doctor may suggest treatment with certain medicines to speed up the removal of AUBERIF from the body, as this may decrease the risk to your baby.

Breastfeeding

Do not take AUBERIF when you are breastfeeding, as teriflunomide may pass into the breast milk.

Contraception

Use in females:

You must use an effective method of contraception (birth control) during and after treatment with AUBERIF. Ask your doctor about reliable methods of birth control that you should use during and after treatment.
The active substance of AUBERIF, teriflunomide, remains in your blood for a long time after you stop taking it, so continue using effective birth control until your blood levels of AUBERIF have been checked to be sufficiently low.

Use in males:

The risk of causing harm to the unborn baby by men using AUBERIF is low, however you should use reliable barrier contraception while taking AUBERIF.

Driving and using machines

Your doctor will tell you whether your illness allows you to drive vehicles and use machines safely. AUBERIF is not expected to have an influence on your ability to drive and use machines.

AUBERIF contains lactose

AUBERIF contains lactose monohydrate, which is a type of sugar.

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking AUBERIF.

3. How to take AUBERIF

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

Your treatment with AUBERIF will be overseen by a doctor who is experienced in the treatment of multiple sclerosis.

Always take AUBERIF exactly as your doctor has instructed you.

You should check with your doctor or pharmacist if you are unsure.

The usual dose is one tablet per day.

You should swallow the tablet whole with some water.

AUBERIF may be taken with or without food.

Use in children and adolescents:

AUBERIF is not intended to be used in children and adolescents below 18 years old (see **Warnings and precautions** above).

If you take more AUBERIF 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 remaining tablets with you so the doctor will know what you have taken.

You may experience side effects similar to those described in section 4 below.

If you forget to take AUBERIF

If you forget to take a dose of AUBERIF, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and continue to take your next tablet at the usual time.

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

If you stop taking AUBERIF

Do not stop taking AUBERIF or change your dose without talking to your doctor first.

If you have any further questions on the use of AUBERIF, ask your doctor, nurse or pharmacist.

4. Possible side effects

AUBERIF can have side effects.

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

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

Frequency unknown:

- severe allergic reactions which might include symptoms of rash, hives, swelling of lips, tongue or face or sudden difficulty breathing or fainting
- severe skin reactions which might include symptoms of skin rash, pain, flu-like symptoms,

fever, peeling or blistering of your mouth, nose, eyes or genitals.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to AUBERIF. 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:

Frequent:

- severe infections or sepsis (a potentially life-threatening type of infection) which might include symptoms of high fever, shaking, chills, reduced urine flow, or confusion
- serious liver disease which might include symptoms of yellowing of your skin or the whites of your eyes, darker urine than normal, unexplained nausea and vomiting, or abdominal pain.

Frequency unknown:

- inflammation of the lungs which might include symptoms of shortness of breath or persistent cough
- inflammation of your pancreas which might include symptoms of severe pain in the upper abdominal area that may also be felt in your back, nausea or vomiting.

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

Tell your doctor if you notice any of the following:

Frequent:

- influenza, upper respiratory tract infection, urinary tract infection, bronchitis, sinusitis, sore throat and discomfort when swallowing, bladder infection, viral gastroenteritis, oral herpes, tooth infection, laryngitis, fungal infection of the foot
- headache
- feeling weak, pins and needles, numbness, tingling or pain in the lower back or leg (sciatica); feeling numb, burning, tingling or pain in the hands and fingers (carpal tunnel syndrome); increased feeling or sensitivity, especially in the skin; stabbing or throbbing pain along one or more nerves

- diarrhoea, feeling sick (nausea), being sick (vomiting), upper abdominal (stomach) pain, toothache
- hair thinning
- rash or itching
- acne
- abnormal blood test results, increase in the liver enzymes (AST, ALT and GGT) which shows changes in the way the liver is working; a decrease in the number of red blood cells (anaemia) and a decrease in white blood cells (this may increase the risk of infection)
- decreased weight
- mild allergic reactions (such as seasonal allergy)
- feeling anxious
- increase in blood pressure
- fast or throbbing heartbeat
- pain of the joints, bones or muscle pain (musculoskeletal pain)
- frequent urge to urinate
- heavy menstrual periods
- pain and post-traumatic pain.

Frequency unknown:

- painful sores with swelling and redness inside the mouth
- colitis (inflammation of the large intestine [the colon])
- psoriasis (long-term [chronic] scaling disease of the skin which may include raised bumps on the skin or affect your nails)
- nail disorders.

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

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can report any side effects directly to Sanofi's Pharmacovigilance Unit at za.drugsafety@sanofi.com (email) or 011 256 3700 (tel).

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

5. How to store AUBERIF

Store all medicines out of reach of children.

Do not use after the expiry date which is stated on the carton, protective sleeve and blister. The expiry date refers to the last day of that month.

Store at or below 30 °C.

Keep the blister in wallet/carton until required for use.

Do not dispose of unused medicines in drains, sewerage systems or household waste.

Return all unused medicine to your pharmacist.

6. Contents of the pack and other information

What AUBERIF contains

The active substance is teriflunomide. Each film-coated tablet contains 14 mg of teriflunomide.

The other ingredients are: hypromellose, hydroxypropyl cellulose, indigo carmine aluminium lake (E132), lactose monohydrate, macrogol, magnesium stearate, maize starch, microcrystalline cellulose, sodium starch glycollate (Type A), talc, titanium dioxide (E171).

Contains sugar (76 mg lactose monohydrate per tablet).

What AUBERIF looks like and contents of the pack

AUBERIF 14 mg film-coated tablets are pale blue to pastel blue, pentagonal film-coated tablets with imprint on one side (dose strength given as number 14) and engraved with corporate logo

on other side.

AUBERIF is available in cardboard cartons containing 28 and 84 tablets in wallet packs with silver aluminium-aluminium blisters.

Holder of Certificate of Registration

sanofi-aventis south africa (pty) ltd

Hertford Office Park, Building I, 5th Floor

90 Bekker Road, Vorna Valley

Midrand 2196

South Africa

Tel: 011 256 3700

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