696 mm

395 mm

197,5 mm

Package leaflet: Information for the patient

Dawnzera 80 mg solution for injection in pre-filled pen
donidalorsen

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Dawnzera is and what it is used for

Dawnzera is a type of medicine called an antisense oligonucleotide inhibitor that contains the active substance donidalorsen. It is used in patients 12 years and older with hereditary angioedema (HAE).to prevent angioedema attacks.

HAE is an inherited condition where the blood does not have enough of a protein called 'C1 inhibitor' or where the C1 inhibitor does not work properly. This leads to too much 'plasma kallikrein', which in turn produces higher levels of a substance called bradykinin in your bloodstream. High levels of bradykinin causes blood vessels to widen and leak fluid into the surrounding tissue leading to the swelling attacks seen in HAE. Symptoms may include stomach pains and swelling of the hands and feet, face, eyelids, lips or tongue, voice-box (larynx), which may make breathing difficult, genitals stomach and intestines

The active substance in Dawnzera, donidalorsen, blocks the activity of plasma kallikrein, which helps to reduce the amount of bradykinin in the bloodstream and prevents symptoms of HAE.

2. What you need to know before you use Dawnzera

Do not use Dawnzera

If you are allergic to donidalorsen or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Dawnzera.
Dawnzera can cause serious allergic reactions (see section 4). If you have a severe allergic reaction to Dawnzera seek emergency medical assistance **immediately**. Symptoms may include:
- rash
- difficulties in breathing
- tight chest
- wheezing
- swelling around the mouth
- fast heart beat

Dawnzera is not meant to be used during an acute HAE attack. If you experience a breakthrough HAE attack, you should use your regular rescue medicine to treat it.

Children and adolescents

Dawnzera is not recommended for use in children under 12 years. It has not been studied in this age group.

Other medicines and Dawnzera

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
Dawnzera is not known to affect other medicines or be affected by other medicines.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

There is limited information on the safety of Dawnzera during pregnancy and breast-feeding. As a precautionary measure, it is preferable to avoid the use of donidalorsen during pregnancy.

This medicine may pass into breast milk and it is not known if this medicine can affect your baby. Your doctor will discuss with you whether to stop treatment with this medicine while you are breast-feeding, or to stop breast-feeding.

Your doctor will discuss with you the risks and benefits of using this medicine.

Driving and using machines

This medicine has no or negligible influence on the ability to drive and use machines.

Dawnzera contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per pre-filled pen, that is to say essentially 'sodium-free'.

3. How to use Dawnzera

Always use use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Dawnzera is a solution provided in a single-use pre-filled pen for injection.

How much Dawnzera to use

The recommended dose is one pre-filled pen once a month. If you have not had an attack for a long period, your doctor may change the dose to one pen every 2 months.

How to inject Dawnzera

Your treatment will be started and managed under the supervision of a doctor experienced in the care of patients with HAE. You or a caregiver can inject this medicine after appropriate training. A doctor, pharmacist or nurse should show you how to prepare and inject Dawnzera properly before you use it for the first time. Do not inject yourself or someone else until you have been trained to inject the medicine.

If you inject Dawnzera yourself or if your caregiver injects it, you or your caregiver must carefully read and follow the detailed instructions in the "Instructions for use".

- Dawnzera should be injected under the skin (subcutaneous injection).
- **Do not** inject
  - within 5 cm of the belly button (navel).
  - into skin that is tender, bruised, red, hard, infected or discoloured.
  - into scars or damaged skin.
- Insert the needle into the fatty tissue in the tummy (abdomen), the front of the thigh or the back of the upper arm.
- Injections in the back of the upper arm must only be given by caregivers.
- Inject the medicine in a different place each time.
- Use each pre-filled pen of Dawnzera only once.

If you use more Dawnzera than you should

Tell your doctor, pharmacist or nurse if you use too much Dawnzera.

If you forget to use Dawnzera

Do not use a double dose to make up for a forgotten dose.

Use the missed dose as soon as you remember. Thereafter resume dosing at the prescribed dosing frequency (once monthly or once every 2 months) from the date of the most recently administered dose.

If you stop using Dawnzera

It is important that you keep injecting Dawnzera as instructed by your doctor, even if you feel better.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

This medicine may cause a severe allergic reaction (with a **common** frequency: may affect up to 1 in 10 people). If you have a severe allergic reaction, **tell your doctor, pharmacist or nurse immediately.** Symptoms include:
- rash
- difficulties in breathing
- tight chest
- wheezing
- swelling around your mouth
- fast heart beat

Tell your doctor, pharmacist or nurse if you notice any of the following side effects.

Very common (may affect more than 1 in 10 people)
- Reactions where the injection is given. Symptoms may include redness, change in skin colour, pain, itching, hardening, haematoma (bleeding under the skin at the site of the injection), bruising, scaling of the skin, allergic reaction or swelling.
- Blood tests showing liver changes.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Dawnzera

Keep this medicine out of the sight and reach of children.

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

Store in a refrigerator (2 °C – 8 °C). Keep the pre-filled pen in the outer carton in order to protect from light.

The pre-filled pen may be stored at room temperature (up to 30 °C) for a single period of up to 6 weeks, but not beyond the expiry date.

If you store Dawnzera at room temperature, write the discard date on the original carton. The discard date is maximally 6 weeks after you take the medicine out of the refrigerator, and should be noted in the space indicated on the original carton for storage at room temperature up to 30 °C.

Do not use this medicine if you notice the following:
- clear cap is missing or not attached.
- expiry date (EXP) or discard date has passed.
- medicine looks frozen, cloudy, discoloured, or has particles.
- pre-filled pen appears damaged.

Do not throw away any medicines via household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Dawnzera contains

- The active substance is donidalorsen. Each pre-filled pen contains 80 mg donidalorsen (as donidalorsen sodium) in 0.8 mL solution.
- The other ingredients are sodium dihydrogen phosphate (E 339), disodium hydrogen phosphate (E 339), sodium chloride, water for injections, hydrochloric acid (E 507) (for pH adjustment), sodium hydroxide (E 524) (for pH adjustment) – see section 2 "Dawnzera contains sodium".

What Dawnzera looks like and contents of the pack

Dawnzera is a clear, colourless to yellow solution for injection in a pre-filled pen.

Dawnzera is available as:
- a single pack containing one pre-filled pen in a carton
- a single pack containing three pre-filled pens in a carton

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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1101 CT Amsterdam
Netherlands

Manufacturer

Tjoapack Netherlands B.V
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Dawnzera
80 mg solution for injection in pre-filled pen
donidalorsen

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Key
KEYLINE
TEXT AREA
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DO NOT REMOVE FROM ARTWORK

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Black

TECHNICAL COLOURS
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Technical Info (Non-Printing)
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