Package leaflet: Information for the patient

Dectova 10 mg/mL solution for infusion
zanamivir

▼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 are given 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 or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Dectova is and what it is used for

Dectova contains zanamivir, which belongs to a group of medicines called antivirals.
Dectova **is used to treat severe flu** (influenza virus infection). It is used when other flu treatments are not suitable.
Adults and children aged 6 months or more can be treated with Dectova.

2. What you need to know before you are given Dectova

Do not use Dectova:
- **if you are allergic** to zanamivir or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Serious skin or allergic reactions

Serious skin or allergic reactions may occur after Dectova is given. Symptoms may include skin or throat swelling, difficulty breathing, blistering rash or peeling skin (see also '*Serious skin or allergic reactions*' in section 4).

Sudden changes in behaviour, hallucinations and fits

During treatment with Dectova, changes in behaviour such as confusion and unresponsiveness may occur. Some people may also have hallucinations (seeing, hearing, or feeling things that are not there) or fits (seizures) which can lead to loss of consciousness. These symptoms also occur in people with flu who are not being given Dectova. So it is not known if Dectova played a part in causing them.

If you notice any of the above symptoms:

➔ **Tell a doctor or nurse immediately.**

Other medicines and Dectova
Tell your doctor if you are taking, have recently taken or might take any other medicines.

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

Driving and using machines
Dectova should not affect your ability to drive or use machines.

Dectova contains sodium
This medicine contains 70.8 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 3.54% of the recommended maximum daily intake of sodium for an adult.

3. How Dectova is given

How much Dectova is given
Your doctor will decide how much Dectova is right for you. The amount you are given is based on your age, body weight, and the results of your blood tests (to check how well your kidneys are working).

Your dose may be increased or decreased depending on how well you respond to treatment.

Adults
The recommended dose is 600 mg twice daily for 5 to 10 days.

If your kidneys are not working as well as they should, your doctor will decide on the reduced dose for you.

Children
Your doctor will decide on the correct dose of Dectova.

When and how Dectova is given
Dectova should be given as soon as possible, usually within 6 days of the symptoms of flu appearing.

A doctor or nurse will give you Dectova as an infusion (drip) into a vein. It is usually given into your arm over about 30 minutes.

If you have any questions on the use of Dectova, ask the doctor or nurse who is giving it you.

If you are given more Dectova than you should
It is unlikely that you will be given too much, but if you think you have been given too much Dectova, **tell your doctor or nurse immediately.**

4. Possible side effects

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

Serious skin and allergic reactions may occur with Dectova, but there isn't enough information to estimate how likely they are. Contact your doctor or nurse straight away if you notice any of the following serious side effects:

- very severe skin reactions such as:
    - a skin rash, which may blister, and looks like small targets (erythema multiforme)
    - a widespread rash with blisters and peeling skin, particularly occurring around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome)
    - extensive peeling of the skin on much of the body surface (toxic epidermal necrolysis).
- severe allergic reactions, including features such as itchy rash, swelling of the face, throat or tongue, breathing difficulty, light headedness and vomiting.

Common side effects
These may affect **up to 1 in 10** people

- diarrhoea
- liver damage (hepatocellular injury)
- rash.

Common side effects that may show up in your blood tests:

- increase in the level of liver enzymes (raised aminotransferases).

Uncommon side effects
These may affect up to **1 in 100** people

- itchy, bumpy rash (hives).

Uncommon side effects that may show up in your blood tests:

- increase in the level of liver or bone enzymes (raised alkaline phosphatase).

Side effects where it is not known how likely they are to happen
There isn't enough information to estimate how likely these side effects are:

- acting strangely
- seeing, hearing or feeling things which are not there
- confused thinking
- fits (seizures)
- being less alert or not responding to loud sounds or being shaken

Reporting of side effects
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme Website: 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 Dectova

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 carton and vial after EXP.

Vials of Dectova are for single use only. Any unused solution should be discarded.

6. Contents of the pack and other information

What Dectova contains

The active substance is zanamivir.
Each mL of Dectova contains 10 mg of zanamivir (as hydrate). Each vial contains 200 mg of zanamivir (as hydrate).
Other ingredients are sodium chloride and water for injections.

What Dectova looks like and contents of the pack
Dectova is a clear, colourless solution for infusion containing 200 mg zanamivir (as hydrate) in 20 mL. It is supplied in a 26 mL clear glass vial with a rubber stopper and an aluminium over-seal with a plastic flip off cap.

There is 1 vial in each pack.

Marketing Authorisation Holder
GlaxoSmithKline Trading Services Limited
12 Riverwalk
Citywest Business Campus
Dublin 24
Ireland

Manufacturer
Glaxo Operations UK Ltd (trading as Glaxo Wellcome Operations)
Harmire Road
Barnard Castle
County Durham
DL12 8DT
UK

Or

GlaxoSmithKline Manufacturing S.P.A
Strada Provinciale Asolana, 90
43056 San Polo di Torrile
Parma
Italy

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

België/Belgique/Belgien
GlaxoSmithKline Pharmaceuticals s.a./n.v.
Tél/Tel: + 32 (0) 10 85 52 00

Lietuva
GlaxoSmithKline Lietuva UAB
Tel: + 370 5 264 90 00
info.lt@gsk.com

България
ГлаксоСмитКлайн ЕООД
Тел.: + 359 2 953 10 34

Luxembourg/Luxemburg
GlaxoSmithKline Pharmaceuticals s.a./n.v.
Belgique/Belgien
Tél/Tel: + 32 (0) 10 85 52 00

Česká republika
GlaxoSmithKline, s.r.o.
Tel: + 420 222 001 111
cz.info@gsk.com

Magyarország
GlaxoSmithKline Kft.
Tel.: + 36 1 225 5300

Danmark
GlaxoSmithKline Pharma A/S

Malta
GlaxoSmithKline (Malta) Limited

Tlf: + 45 36 35 91 00
dk-info@gsk.com

Deutschland
GlaxoSmithKline GmbH & Co. KG
Tel.: + 49 (0)89 36044 8701
produkt.info@gsk.com

Eesti
GlaxoSmithKline Eesti OÜ
Tel: + 372 6676 900
estonia@gsk.com

Ελλάδα
GlaxoSmithKline A.E.B.E.
Τηλ: + 30 210 68 82 100

España
GlaxoSmithKline, S.A.
Tel: + 34 902 202 700
es-ci@gsk.com

France
Laboratoire GlaxoSmithKline
Tél: + 33 (0)1 39 17 84 44
diam@gsk.com

Hrvatska
GlaxoSmithKline d.o.o.
Tel: + 385 1 6051 999

Ireland
GlaxoSmithKline (Ireland) Limited
Tel: + 353 (0)1 4955000

Ísland
Vistor hf.
Sími: +354 535 7000

Italia
GlaxoSmithKline S.p.A.
Tel: + 39 (0)45 9218 111

Κύπρος
GlaxoSmithKline (Cyprus) Ltd
Τηλ: + 357 22 397000
gskcyprus@gsk.com

Latvija
GlaxoSmithKline Latvia SIA
Tel: + 371 67312687

Tel: + 356 21 238131

Nederland
GlaxoSmithKline BV
Tel: + 31 (0)30 6938100
nlinfo@gsk.com

Norge
GlaxoSmithKline AS
Tlf: + 47 22 70 20 00

Österreich
GlaxoSmithKline Pharma GmbH
Tel: + 43 (0)1 97075 0
at.info@gsk.com

Polska
GSK Services Sp. z o.o.
Tel.: + 48 (0)22 576 9000

Portugal
GlaxoSmithKline – Produtos Farmacêuticos, Lda.
Tel: + 351 21 412 95 00
FI.PT@gsk.com

România
GlaxoSmithKline (GSK) S.R.L.
Tel: + 4021 3028 208

Slovenija
GlaxoSmithKline d.o.o.
Tel: + 386 (0)1 280 25 00
medical.x.si@gsk.com

Slovenská republika
GlaxoSmithKline Slovakia s. r. o.
Tel: + 421 (0)2 48 26 11 11
recepcia.sk@gsk.com

Suomi/Finland
GlaxoSmithKline Oy
Puh/Tel: + 358 (0)10 30 30 30
Finland.tuoteinfo@gsk.com

Sverige
GlaxoSmithKline AB
Tel: + 46 (0)8 638 93 00
info.produkt@gsk.com

United Kingdom
GlaxoSmithKline UK Ltd
Tel: + 44 (0)800 221441

lv-epasts@gsk.com customercontactuk@gsk.com

This leaflet was last revised in 10/2019.

This medicine has been authorised under 'exceptional circumstances'.
This means that for scientific reasons it has not been possible to get complete information on this medicine. The European Medicines Agency will review any new information on this medicine every year and this leaflet will be updated as necessary.

Other sources of information
Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu

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The following information is intended for healthcare professionals only:

7. INFORMATION FOR HEALTHCARE PROFESSIONALS

Dectova preparation

- The volume of Dectova and total volume for infusion will depend on the patient's age, weight and renal function (see section 4.2 of the SmPC).
- The dose can be infused as supplied or diluted in sodium chloride 9 mg/mL (0.9%) solution for injection down to any concentration greater than or equal to 0.2 mg/mL.
- Each vial is for single use only; once the seal has been broken, the remaining volume must be discarded.

How to prepare the infusion for intravenous administration:

- Use aseptic techniques throughout preparation of the dose.
- Calculate the required dose and volume of Dectova.
- Decide on the volume of sodium chloride 9 mg/mL (0.9%) solution for injection to be used for infusion.
- Using a sterile needle and syringe, withdraw and discard a volume of sodium chloride 9 mg/mL (0.9%) solution for injection (equal to the volume of Dectova) from the infusion bag.
- Infusion bags may have a further overage of sodium chloride 9 mg/mL (0.9%) solution for injection included – this can also be removed if considered necessary.
- Using a sterile needle and syringe, withdraw the volume of Dectova from the vial(s) and add to the infusion bag.
- Discard any unused portion of the vial.
- The infusion bag should be gently manipulated by hand to ensure it is mixed thoroughly.
- If refrigerated, the infusion bag should be removed from the refrigerator and brought up to room temperature before use.