

## Package leaflet: Information for the patient

### Trogarzo 200 mg concentrate for solution for infusion ibalizumab

▼ 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 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 Trogarzo is and what it is used for
2. What you need to know before you use Trogarzo
3. How to receive Trogarzo
4. Possible side effects
5. How to store Trogarzo
6. Contents of the pack and other information

#### **1. What Trogarzo is and what it is used for**

##### **What Trogarzo is**

Trogarzo contains the active substance ibalizumab. This is a type of protein called a ‘monoclonal antibody’ that can attach to a specific target in the body. It belongs to a group of medicines called ‘antiretrovirals’.

##### **What Trogarzo is used for**

Trogarzo is used in adults to treat HIV infection that has not responded to a number of HIV treatments in the past.

Your doctor has prescribed Trogarzo to help control your HIV infection.

Trogarzo is used in combination with other medicines.

It will be used together with other HIV medicines called ‘antiretrovirals’.

##### **How Trogarzo works**

The HIV virus infects cells in your blood called ‘CD4’ or ‘T-cells’. Trogarzo attaches to the CD4 receptor and blocks HIV from entering and infecting your blood cells. This will reduce the amount of virus in your body, and keeps it at a low level. This helps your body to increase the CD4 cell count in your blood. CD4 cells are a type of white blood cell that are important in helping your body to fight infection.

#### **2. What you need to know before you use Trogarzo**

##### **You must not be given Trogarzo:**

- if you are allergic to ibalizumab or any of the other ingredients of this medicine (listed in section 6).

If you are not sure, talk to your doctor or nurse before being given Trogarzo.

## Warnings and precautions

### Look out for side effects

Trogarzo can cause serious side effects that you need to tell your doctor or nurse about straight away. These include:

- **signs of a new infection** (called ‘immune reconstitution inflammatory syndrome’)

Tell your doctor or nurse straight away if you get any of the above (for more information see ‘Serious side effects’ in section 4).

### Passing HIV to others

This medicine reduces the amount of HIV in your body. When this is stably kept at undetectable levels, the chances that you can still pass on HIV to your sexual partners become negligible. You can still pass on HIV when taking this medicine, if you have detectable levels of HIV in your body. Talk to your doctor or nurse about how to avoid infecting other people.

### Children and adolescents

Do not give this medicine to children and adolescents below 18 years of age. This is because Trogarzo has not been studied in this age group.

### Other medicines and Trogarzo

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

### Pregnancy

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

If you could get pregnant while taking Trogarzo, you need to use a reliable method of barrier contraception (for example, a condom) with other methods of contraception including oral contraceptive (the pill) or other hormonal contraceptives (for example, implants or injections), to prevent pregnancy.

### Breast-feeding

**Women who are HIV-positive must not breast feed** because HIV infection can be passed on to the baby in breast milk. It is unknown if Trogarzo can pass into breast milk.

If you are breast-feeding, or thinking about breast-feeding:

→ **Talk to your doctor immediately.**

### Driving and using machines

Do not drive or use machines after you have been given Trogarzo if you do not feel well enough. Headache, feeling dizzy, feeling sick (nausea) or feeling tired are common side effects of Trogarzo and can affect your ability to drive or use machines.

### Trogarzo has a low sodium content

Trogarzo contains less than 1 mmol sodium (23 mg) in each dose and therefore is essentially sodium-free.

## 3. How to receive Trogarzo

You will be given Trogarzo under the supervision of an experienced doctor or nurse.

Trogarzo is used in combination with other medicines called ‘antiretrovirals’.

### How much Trogarzo you will be given

The recommended dose of Trogarzo is:

- a single dose of 2,000 mg on the first occasion
- followed by a maintenance dose of 800 mg every 2 weeks.

Trogarzo will be added to a drip (infusion bag) containing a sodium chloride (saline) solution before use.

More than one vial of Trogarzo will be needed to get the required dose.

### **How you will be given Trogarzo**

The drip (infusion) will be given into a vein over 15 to 30 minutes. Your doctor or nurse will monitor you during the Trogarzo infusion and for a period of time after your infusion.

### **If you miss a dose of Trogarzo**

- It is very important that you are given Trogarzo every 2 weeks as instructed by your doctor.
- Do not change the schedule of your Trogarzo infusions or any of your other antiretroviral medicines without talking to your doctor first.
- If you miss an appointment, ask your doctor straight away when to schedule your next dose.

### **If you stop having Trogarzo**

Keep having Trogarzo infusions until your doctor tells you to stop. If you stop and there is a gap in your treatment, the level of HIV virus in your blood may begin to rise. This is less likely if you receive Trogarzo regularly and without gaps in treatment.

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

## **4. Possible side effects**

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

### **Serious side effects**

Talk to your doctor or nurse straight away if you get any of the following serious side effects:

- Signs of a new infection, changes in your immune system, can happen when you start using HIV medicines. Your immune system might get stronger and begin to fight infections that have been hidden in your body for a long time (this is called 'immune reconstitution inflammatory syndrome'). Look out for new signs of infection after receiving Trogarzo; these can be different from person to person depending on the type of infection that was hidden and might include fever, headache, difficulty breathing, stomach ache, coughing and swollen glands (lumps and bumps on your body, neck, armpit or groin).
- Allergic reaction (hypersensitivity).

### **Other side effects**

Tell your doctor or nurse if you notice any of the following side effects:

**Common** (may affect up to 1 in 10 people):

- skin rash
- diarrhoea
- feeling sick (nausea) or being sick (vomiting)
- dizziness
- headache
- feeling tired
- dry skin
- dermatitis – a type of eczema with dry itchy skin
- pain and feeling numb in hands, feet or legs

**Uncommon** (may affect up to 1 in 100 people):

- tremor
- feeling dizzy, faint or light headed when standing up
- dry mouth
- feeling hot
- spots or swelling
- itchy skin, or skin damage
- bruising
- abnormal heartbeat
- high blood pressure or frequent changes in blood pressure

Seen in tests:

- abnormal results on tests of the heart's electrical activity (electrocardiogram)

Tell your doctor or nurse if you notice any of the side effects listed above.

### **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 the **national reporting system**:

Yellow Card Scheme

Website: [www.mhra.gov.uk/yellowcard](http://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 Trogarzo**

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 vial label and carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C to 8°C).

Do not freeze.

Store in the original package in order to protect from light.

## **6. Contents of the pack and other information**

### **What Trogarzo contains**

- The active substance is ibalizumab.
- One vial contains 200 mg of ibalizumab in 1.33 mL of solution.
- The other excipients are sucrose, sodium chloride (see section 2 'Trogarzo has a low sodium content'), polysorbate 80, histidine, hydrochloric acid, water for injections.

### **What Trogarzo looks like and contents of the pack**

Trogarzo is a colourless to slightly yellow, clear to slightly opalescent concentrate for solution for infusion (sterile concentrate), with no visible particles.

The pack size is 2 glass vials per carton.

**Marketing Authorisation Holder and manufacturer**

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**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:

Method of administration

Intravenous use

Diluted ibalizumab solution should be administered by a healthcare professional.

Ibalizumab should be administered as an intravenous infusion. Ibalizumab should not be administered as an intravenous push or bolus.

The duration of the first infusion (loading dose) should be no less than 30 minutes. If no infusion-associated adverse reactions have occurred, the duration of the subsequent infusions (maintenance doses) can be decreased to no less than 15 minutes.

After the infusion is complete, flush with 30 mL of sodium chloride 9 mg/mL (0.9%) solution for injection.

All patients must be observed during and for 1 hour after completion of ibalizumab administration for at least the first infusion. If a reaction occurs, the infusion should be discontinued and appropriate medical therapies should be administered. Prophylactic medication is not warranted prior to each infusion. If the patient does not experience an infusion-associated adverse reaction, the post-infusion observation time can be reduced to 15 minutes thereafter.

Instructions on dilution of ibalizumab before use

Ibalizumab is administered intravenously (IV), after diluting the appropriate number of vials in 250 mL of sodium chloride 9 mg/mL (0.9%) solution for injection. See the table below for the appropriate number of vials required to prepare both the loading dose of 2,000 mg and the maintenance doses of 800 mg.

**Recommended ibalizumab dose and number of vials per administration**

Ibalizumab dose	Ibalizumab vials (total volume to be withdrawn)
Loading dose of 2,000 mg	10 vials (13.3 mL)
Maintenance dose of 800 mg	4 vials (5.32 mL)

Ibalizumab concentrate for solution for infusion should be prepared by a healthcare professional using aseptic technique as follows:

- Remove the flip-off cap from the vial and wipe with an alcohol swab.
- Insert sterile syringe needle into the vial through the center of the stopper and withdraw 1.33 mL from each vial (NOTE: a small residual amount may remain in the vial, discard unused portion) and transfer into a 250 mL intravenous bag of sodium chloride 9 mg/mL (0.9%) solution for injection. Other intravenous diluents must not be used to prepare the ibalizumab solution for infusion.
- Once diluted, the ibalizumab solution should be administered immediately.
- Discard partially used vials or empty vials of ibalizumab and any unused portion of the diluted ibalizumab solution in accordance with local requirements.

Precautions to be taken before handling or administering the medicinal product

This medicinal product should be inspected visually for particulate matter and discoloration prior to administration. Vials containing non-diluted ibalizumab or infusion bag containing diluted ibalizumab must be discarded if solution is cloudy, if there is pronounced discoloration or if there is foreign particulate matter.