

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC:
SN:
NN:

Medicinal product no longer authorised

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Inner carton without Blue Box

1. NAME OF THE MEDICINAL PRODUCT

Victrelis 200 mg hard capsules
boceprevir

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each hard capsule contains 200 mg boceprevir.

3. LIST OF EXCIPIENTS

Also contains lactose.
See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

84 hard capsules. Component of a multipack, can't be sold separately

5. METHOD AND ROUTE(S) OF ADMINISTRATION



Oral use.
Do not push through blister.
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

- Store in a refrigerator until expiry.
- OR
- Store outside of the refrigerator at or below 30°C for a period of not more than 3 months until expiry.
- Store in the original blister in order to protect from moisture.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

Any unused product or waste material should be disposed of in accordance with local requirements

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Merck Sharp & Dohme Ltd
Hertford Road, Hoddesdon
Hertfordshire EN11 9BU
United Kingdom

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/11/704/001

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Victralis

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MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE MEDICINAL PRODUCT

Victrelis 200 mg hard capsules
boceprevir

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Merck Sharp & Dohme Ltd

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER



Open here

Medicinal product no longer authorised

Medicinal product no longer authorised

B. PACKAGE LEAFLET

Package leaflet: Information for the user

Victrelis 200 mg hard capsules boceprevir

Read all of this leaflet carefully before you start taking 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 pharmacist.
- This medicine has been prescribed for you. 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Victrelis is and what it is used for

What Victrelis is

Victrelis contains the active ingredient boceprevir which helps to fight against hepatitis C infection by stopping the virus multiplying. Victrelis must always be used together with two other medicines. These are called peginterferon alfa and ribavirin. Victrelis must not be used by itself.

What Victrelis is used for

Victrelis, in combination with peginterferon alfa and ribavirin, is used for chronic hepatitis C virus infection in adults (also called HCV infection).

Victrelis may be used in adults who are previously untreated for HCV infection or who have previously used medicines called 'interferons' and 'pegylated interferons'.

How Victrelis works

Victrelis inhibits the direct replication of the virus and contributes in this way to lowering the amount of hepatitis C virus in your body.

2. What you need to know before you take Victrelis

Do not take Victrelis in combination with peginterferon alfa and ribavirin if you:

- are **allergic** to boceprevir or any of the other ingredients of this medicine (listed in section 6)
- are **pregnant**
- have a condition called 'autoimmune hepatitis'
- are taking bepridil, pimozide, lurasidone, oral midazolam, oral triazolam, simvastatin, lovastatin, alfuzosin, silodosin, 'ergot' type medicines (such as dihydro-ergotamine, ergonovine, ergotamine or methylergonovine), lumefantrine, halofantrine, quetiapine, or tyrosine kinase inhibitors.

Do not take Victrelis if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Victrelis.

Reminder: Please also read the "Do not use" section of the Package Leaflets for peginterferon alfa and ribavirin before you start taking Victrelis.

Warnings and precautions

Talk to your doctor or pharmacist before taking your medicine if you:

- have ever had a blood problem such as **anaemia** (when you lack enough healthy red blood cells, which transport oxygen around your body)
- have ever had a blood problem such as neutropenia (lack of a certain type of white blood cells). Neutropenia affects the body's ability to fight off infections
- have ever had a blood problem such as pancytopenia (a combination of low platelet, red and white blood cell counts)
- have a current or previous infection with the hepatitis B virus, since your doctor may want to monitor you more closely
- have liver failure
- have another **liver** problem in addition to hepatitis C infection
- have **HIV** (human immunodeficiency virus) or have ever had any other problems with your immune system
- were an organ transplant recipient
- have hepatitis C other than genotype 1
- were a patient who has previously failed treatment with an HCV protease inhibitor
- have or anyone in your family has an irregular heartbeat, especially a condition called "QT prolongation"
- have low blood potassium (hypokalaemia)

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Victrelis.

While taking the combination of Victrelis with ribavirin and peginterferon alpha, serious allergic reactions have been reported. Please see "Possible side effects" for more information.

Tests

Your doctor will have your blood tested regularly. These blood tests are done for a number of reasons:

- so your doctor knows if the treatment is working for you
- to help your doctor decide how long you will be treated with Victrelis.
- to check for side effects.

Other medicines and Victrelis

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription and herbal medicines.

In particular, do not take Victrelis if you are taking any of the following medicines:

- alfuzosin and silodosin – used to treat symptoms of an enlarged prostate
- bepridil – used for heart problems
- pimozone or lurasidone – used for mental health problems
- oral midazolam or oral triazolam – a sedative, given by mouth
- statins – simvastatin or lovastatin
- 'ergot' type medicines, such as dihydro-ergotamine, ergonovine, ergotamine or methylethylergonovine – used for migraine and cluster headaches
- lumefantrine and halofantrine – anti-malaria medicines
- quetiapine - used to treat schizophrenia, bipolar disorder and major depressive disorder
- tyrosine kinase inhibitors – used as anti-cancer medicines

Do not take Victrelis if you are taking any of the medicines above. If you are not sure, talk to your doctor or pharmacist before taking Victrelis.

Also, tell your doctor or pharmacist if you are taking any of the following:

- birth control medicines - drospirenone
- CYP3A4 inducer medicines (such as antibiotic medicine - rifampicin, and anticonvulsant medicines - carbamazepine, phenobarbital, phenytoin)
- antiarrhythmic medicines- amiodarone, quinidine
- antimicrobial medicine – pentamidine
- some neuroleptics
- antifungal medicines - ketoconazole, itraconazole, posaconazole, voriconazole
- HIV non-nucleoside reverse transcriptase inhibitor – efavirenz, etravirine
- HIV protease inhibitors – atazanavir, darunavir, lopinavir, ritonavir
- intravenous sedatives - benzodiazepines (e.g., alprazolam, midazolam, triazolam)
- immunosuppressants – tacrolimus, sirolimus, cyclosporine
- select statins - atorvastatin or pravastatin
- methadone
- hormonal replacement therapy - oestrogen-based medicines
- medicine used to decrease blood pressure - calcium channel blockers (e.g., amlodipine, diltiazem, felodipine, nicardipine, nifedipine, nisoldipine, verapamil)
- medicine used to treat symptoms of an enlarged prostate – doxazosin and tamsulosin
- warfarin and other similar medicines called vitamin K antagonists used to thin the blood. Your doctor may need to increase the frequency of your blood tests to check how well your blood can clot.

Pregnancy and breast-feeding

Pregnancy must be avoided due to the use of Victrelis with ribavirin. Ribavirin can be very damaging to an unborn baby. Therefore, you and your partner must take **special precautions** in sexual activity if there is any chance for pregnancy to occur:

- if you are a **woman** of childbearing age who is taking ribavirin:
you must have a negative pregnancy test before treatment, each month during treatment, and for the 4 months after treatment is stopped. You must use an effective birth control during the time you are taking ribavirin and for 4 months after stopping treatment. This should be discussed with your doctor.
- if you are a **man** who is taking ribavirin:
do not have sex with a pregnant woman unless you **use a condom**. This will lessen the possibility for ribavirin to be left in the woman's body. If your female partner is not pregnant but is of childbearing age, she must be tested for pregnancy each month during treatment and for the 7 months after treatment has stopped. You or your partner must use an effective birth control during the time you are taking ribavirin and for 7 months after stopping treatment. This should be discussed with your doctor.

It is possible that boceprevir is excreted in human milk. If you are breast-feeding, your doctor will advise you to discontinue breast-feeding or to discontinue Victrelis while breast-feeding.

Reminder: Please also read the “Pregnancy and breast-feeding” section of the Package Leaflets for peginterferon alfa and ribavirin before you start taking Victrelis.

Driving and using machines

Victrelis does not affect your ability to drive or use tools or machines. However, the combination therapy of Victrelis, peginterferon alfa and ribavirin may make you feel tired, faint, a sensation of your head spinning, changes in blood pressure, confused or difficulty seeing clearly. If this happens, do not drive or use any tools or machines.

Victrelis contains lactose

Victrelis contains lactose (a type of sugar). If you have been told by your doctor that you cannot tolerate or digest some sugars (you have an intolerance to some sugars), such as Lapp lactase deficiency, or glucose-galactose malabsorption, talk to your doctor before taking this medicine.

3. How to take Victrelis

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

How much to take

The recommended dose of Victrelis is 4 capsules three times a day (a total of 12 capsules a day). Take the capsules in the morning, afternoon and evening with a meal or light snack. The use without food could seriously compromise your chance of success of treatment.

How to take this medicine

- Peel back the tab to get to the capsule - do not push the capsule through the blister since pushing the capsule through the package may break the capsule.
- Take this medicine by mouth.
- This medicine should be taken with a meal or light snack.
- Victrelis is always taken in combination with peginterferon alfa and ribavirin.
- The duration of the administration of these medicines will depend on your response and treatment plan.

Reminder: Please also read the "Possible side effects" in the Package Leaflets for peginterferon alfa and ribavirin before you start taking Victrelis.

If you take more Victrelis than you should

If you take more Victrelis than you should, talk to a doctor or go to the nearest hospital emergency room straight away.

If you forget to take Victrelis

- If you forget a dose and it is more than 2 hours before your next dose is due, take the missed dose with food. Then continue taking your capsules as normal.
- However, if it is less than 2 hours before your next dose is due, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose.

If you have any questions about what to do, talk to your doctor.

If you stop taking Victrelis

Do not stop taking Victrelis unless your doctor tells you to.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist because your treatment may not work.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Stop taking Victrelis and see a doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment:

- difficulty breathing or swallowing, wheezing, hives, itching, swelling of your face, eyes, lips, tongue or throat – these are signs of an allergic reaction.

Other side effects include:

Very common (may affect more than 1 in 10 people)

General: headache; chills, fever; feeling sick (nausea); flu-like symptoms; feeling dizzy, low energy; not being able to sleep; low appetite, weight loss; shortness of breath

Mouth, nose or throat: cough; dry mouth; funny taste

Skin and hair: dry skin, itching, rash; hair loss or thinning of hair

Joints and muscles: unusual weakness; painful, swollen joints; muscle ache not caused by exercise

Stomach and gut: diarrhoea; being sick (vomiting)

Mental illness: feeling anxious; feeling of deep sadness or of being worthless (depression); feeling irritable, tense and restless

Blood: low red blood cell count (anaemia), drop in the number of red blood cells – the signs may include feeling tired, headaches, being short of breath when exercising; low neutrophil count (neutropenia), low number of white blood cells – the signs may include getting more infections than usual - including fever, severe chills, a sore throat or mouth ulcers

Common (may affect up to 1 in 10 people)

General: shaking; fainting; difficulty breathing; feeling thirsty; trouble sleeping; throbbing headache; generally feeling unwell; feeling like you are spinning

Eyes or ears: dry eyes; ringing in the ears; changes in your vision

Mouth, nose or throat: mouth pain, tooth ache; pain when swallowing; nose bleed, stuffy nose; a change in how things smell; sore and raised patches in the mouth; feeling very thirsty with a dry mouth or dry skin; swelling of the thyroid gland, neck or voicebox; underactive thyroid gland; sores or swelling in the mouth, burning feeling on the tongue; feeling of tension or fullness in the nose, cheeks and behind the eyes - sometimes with a throbbing ache, fever or stuffy nose (sinusitis)

Skin and hair: cold sores, tingling or numbness of the skin; reduced feeling or sense of touch; skin rash, patchy skin rash, red skin; red raised skin rash sometimes with pus-filled blisters; hot, tender and red skin, sometimes with fever and chills; increased sweating; skin disease with thick patches of red skin – often with silvery scales

Joints and muscles: muscle spasm; feeling tired, muscle weakness, feeling cold; back pain, neck pain, pain in the arms or legs

Stomach and gut: pain in stomach and in the upper right side of the stomach or back; a burning feeling in the stomach; upset stomach; feeling bloated, burping (belching)

Anus: wind (flatulence); piles (haemorrhoids); difficulty passing stools (constipation)

Urinary: going to the toilet to urinate more often than usual

Sexual: a decrease in sex drive; difficulty getting or keeping an erection

Mental illness: changes in mood, feeling agitated; memory loss, trouble concentrating

Chest: difficulty breathing; chest discomfort, chest pain; heavy feeling in the chest, with difficulty breathing or wheezing

Heart or circulation: fast or uneven heart-beat; high or low blood pressure

Blood: drop in the number of blood platelets – the signs may include bleeding or bruising more easily than usual; high sugar (glucose) levels in the blood; high triglycerides levels in the blood; high uric acid levels in the blood; a combination of low platelet, red and white blood cell counts (pancytopenia); a severe drop of neutrophil count (agranulocytosis)

Uncommon (may affect up to 1 in 100 people)

General: light-headedness, arthritis; increased tendency to bleed; swollen glands in neck or armpit or groin; intense burning or stabbing pain; increased sensitivity to light, sound, what is felt, or food one tastes; diabetes

Eyes or ears: pink eye; eye pain; deafness; trouble hearing; swelling around the eyelid; increased tearing; fluid draining from the ear or eye; abnormal feeling around the eye, red patch on the white of the eye; yellowing of the white part of the eyes or of the skin

Mouth, nose or throat: hoarseness, dry throat or lips; painful or bleeding gums; sensitive tooth or toothache; tongue swollen, discoloured, or has sores; blistering by the tongue; severe pain

when swallowing; chest pain close to the lungs; chest pain worsens when taking a deep breath; uncontrolled salivating; overactive thyroid gland

Skin and hair: hives; open sore; intolerance to heat; markedly red face; pale face; yellow skin; rash due to sunlight; wound not healing normally

Feet or hands or legs or arms: sensation of pain, numbness, tingling or prickling; blood clot in a vein; feeling cold in an arm or leg; painful inflammation of the joints most commonly in the foot (gout)

Stomach and gut: lower stomach pain; pancreatitis

Urinary: painful when urinating; burning feeling or difficulty urinating; get up several times during the night to urinate

Rectum or anus: anal itching; inability to pass stools or discoloured stools; more frequent bowel movements; bleeding from anus

Sexual: missing menstrual period; heavy or prolonged menstrual period; uterine bleeding (i.e., prolonged >7 days or excessive bleeding at irregular or more frequent than normal intervals, bleeding occurring in menopausal women at least 6 months to 1 year after cessation of cycles)

Mental illness: anger; hostile attitude or behaviour; threatening behaviour; substance abuse problems, abnormal behaviour; feeling of confusion; thoughts of suicide; sudden intense fear or apprehension; feeling you are being persecuted; difficulty solving problems

Muscles: pain in your bones; local or widespread pain

Chest: pneumonia

Heart or circulation: abnormal or rapid heart rate; heart disease caused by poor blood flow in the heart

Blood: low potassium levels in your blood; high calcium levels in the blood

Rare (may affect up to 1 in 1,000 people)

General: difficult breathing and swallowing; tumour of the thyroid; infection of the blood; swelling or lumps in organs of the body; disease which leads to increasing muscle paralysis; disease of the brain – signs may include headache and fever, paralysis of a part of the body, a stiff neck or being sensitive to light

Eyes or ears: ear ache

Skin and hair: reddening of the skin; bacterial skin infection

Stomach and gut: problems digesting food; vomiting blood; vomiting, diarrhoea, and severe right upper corner stomach (hepatic) pain

Sexual: drop in levels of sperm

Mental illness: change in mood; feeling like your life is falling apart; seeing, feeling or hearing things that are not real (hallucinations); thoughts of killing yourself (suicide), trying to kill yourself; feeling of great happiness (mania) and then a feeling of deep sadness or not being worthy

Chest: being short of breath when lying flat; serious lung infection like pneumonia; sharp chest pains which are worse when breathing; pain behind breast bone which can spread to neck and shoulders

Heart or circulation: heart attack; stopping breathing; blood clot in the leg or arm; decreased blood flow to parts of the brain (e.g., dizziness, double vision, or weakness on both sides of the body)

Not known (frequency cannot be estimated from the available data)

Skin and hair: Severe rash, which may be accompanied by fever, fatigue, swelling of the face or lymph glands, increase of eosinophils (type of white blood cells), effects on liver, kidney or lung (a reaction called DRESS); serious skin reaction, including blistering or peeling of the skin (a reaction called Stevens-Johnson syndrome)

Kidney: renal impairment (generally reversible after conclusion of treatment)

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 also report side effects directly via [the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Victrelis

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 blisterfoil after EXP. The expiry date refers to the last day of that month.

Storage by the pharmacist

Store in a refrigerator (2°C – 8°C).

Storage by the patient

- Store in a refrigerator (2°C – 8°C) until expiry.

OR

- Store outside of the refrigerator at or below 30°C for a period of not more than 3 months until expiry. After this period, the medicinal product should be disposed.

Store in the original blister in order to protect from moisture.

Do not throw away any medicine via wastewater or 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 Victrelis contains

- The active substance is boceprevir. Each hard capsule contains 200 mg of boceprevir.
- The other ingredients are sodium lauryl sulfate, microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, pre-gelatinized starch, magnesium stearate, yellow iron oxide (E172), red iron oxide (E172), titanium dioxide (E171), gelatin, and shellac.

What Victrelis looks like and contents of the pack

The hard capsules have a yellowish-brown cap with the "MSD" logo printed in red ink and an off-white body with "504" printed in red ink.

Peelable blister containing 12 hard capsules (3x4 capsule blister strip).

Pack sizes: carton of 84 hard capsules and multipack containing 336 (4 packs of 84) hard capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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