

Package leaflet: Information for the user

Clindamycin Villerton 300 mg solution for infusion Clindamycin Villerton 600 mg solution for infusion clindamycin

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

What is in this leaflet

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

1. What Clindamycin Villerton is and what it is used for

Clindamycin Villerton contains the active substance clindamycin, which is one of a group of medicines called antibiotics.

These are used to kill the bacteria or “germs” that cause infections. Your doctor has decided to give you Clindamycin Villerton because you have an infection.

Clindamycin Villerton is usually reserved for the treatment of severe infections in adults and adolescents older than 12 years when the infection is caused by bacteria that are sensitive to clindamycin, and other antibiotics have been unable to clear the infection.

2. What you need to know before you use Clindamycin Villerton

Do not use Clindamycin Villerton

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

Warning and precautions

Talk to your doctor before using Clindamycin Villerton:

- if you suffer from impaired liver and kidney function,
- if you have problems with your muscle functions caused by e.g. myasthenia gravis (pathological muscular weakness) or Parkinson disease (so called shaking palsy),
- if you have previously suffered from gastrointestinal diseases (e.g. earlier inflammation of the colon),

- if you suffer from any kind of allergies, e.g. hypersensitivity to penicillin because in individual cases allergic reactions to clindamycin have been reported in people with a known penicillin hypersensitivity.

You should consult your doctor if one of the precautions and warnings mentioned above are or were applicable to you in the past.

Severe allergic reactions can occur even after the first treatment. In this event your doctor will discontinue the treatment with clindamycin immediately and will implement standard emergency measures.

In long-term therapy (more than 10 days), the doctor may need to monitor the blood count and the liver and renal function.

Acute kidney disorders may occur. Please inform your doctor about any medication you currently take and if you have any existing problems with your kidneys. If you experience decreased urine output, fluid retention causing swelling in your legs, ankles or feet, shortness of breath, or nausea you should contact your doctor immediately.

During treatment with clindamycin, a severe infection of the colon (colitis) may occur. Therefore, you should **immediately** inform your doctor if you suffer from diarrhoea during or after treatment, especially when mucus or blood are in the stools.

Other medicines and Clindamycin Villerton

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

In particular, tell your doctor if you are using:

- warfarin or similar medicines (e.g. acenocoumarol and fluindione) used to thin the blood. You may be more likely to have a bleed. Your doctor may need to take regular blood tests to check how well your blood can clot.
- Clindamycin Villerton may increase the effect of muscle relaxants which may lead to unexpected, life-threatening incidences during surgery.
- Clindamycin Villerton should not be given with rifampicin, St John's wort (Hypericum perforatum), carbamazepine, phenytoin or phenobarbital, enzalutamide, efavirenz and dabrafenib as this may result in loss of effect.

Pregnancy and breast-feeding

Tell your doctor if:

- you are pregnant or think you might be pregnant.
 - you are breast-feeding This medicine can pass into breast milk. In the breast-fed infant, diarrhoea or blood in the stool, fungal infections and hypersensitivity (allergic reaction) can occur. If this occurs, tell your doctor at once.
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Your doctor will decide whether to use Clindamycin Villerton if you are pregnant or breastfeeding.

Driving and using machines

This medicine may cause mild to moderate side effects that can affect your ability to drive and use machines. You may feel dizzy, tired or suffer from headaches when taking this medicine. If you are affected, do not drive or use any tools or machines.

Clindamycin Villerton contains glucose and sodium

This medicine contains 2.5 g glucose per bag. This should be taken into account in patients with diabetes mellitus.

This medicine contains less than 1 mmol sodium (23 mg) per 50 ml bag volume, that is to say essentially 'sodium-free'.

3. How to use Clindamycin Villerton

Clindamycin Villerton is administered by intravenous infusion (into a vein using a drip). It will usually be given by a doctor or a nurse.

Your doctor will decide on the correct dose of clindamycin for you.

The infusion will take 10 – 60 minutes.

Adults and adolescents older than 12 years are usually given:

- for the treatment of severe infections:

1800 – 2700 mg/day of clindamycin in two or three equal doses.

- for the treatment of less complicated infections:

1200 – 1800 mg/day of clindamycin in two, three or four equal doses.

Use in children

This medicine should not be given to children.

If you use more Clindamycin Villerton than you should

If you think you have received too much medicine, speak to your doctor or nurse.

If you forget to use Clindamycin Villerton

As you will be given this medicine by a doctor or nurse, you are unlikely to miss a dose. If you think you have missed a dose, speak to your doctor or nurse.

4. Possible side effects

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

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

- Gastrointestinal disorders, such as nausea, abdominal pain, vomiting, diarrhoea.

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

- Severe or prolonged or bloody diarrhoea during or after treatment may be a sign of bowel inflammation (pseudo-membranous colitis) which may be caused by antibiotics.

- Blood abnormalities, such as changes in the number of white blood cells (which may make infections more likely) or reduction in blood platelets (which increases risk of bleeding or bruising).
- Diseases of the blood vessels such as inflammation of the veins (thrombophlebitis).
- Skin lesions, such as those with large blistering skin rash (maculo-papular exanthema, morbilliform exanthema), 'nettle rash' (urticaria).
- The results of liver tests may be affected.

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

- Nervous system disturbances, such as an inhibit nerve impulse progression (neuromuscular blocking effect) and altered taste (dysgeusia).
- Difficulty breathing, low blood pressure.
- Pain and abscess at the site of injection.

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

- Fever.
- Serious skin reactions:
 - A large skin rash with blistering and peeling skin, especially around the mouth, nose, eyes, and genitals (Stevens-Johnson syndrome), and a more serious illness with blistering of the skin (toxic epidermal necrolysis or Lyell syndrome).
 - Extensive red skin rash with skin flaking (exfoliative dermatitis, bullous dermatitis, erythema multiforme).
 - Serious allergic reaction which causes swelling of the face or throat (angioedema).
- Itchy skin (pruritus).
- Inflammation of the vaginal mucosa (vaginitis).

Very rare side effects (may affect up to 1 in 10,000 people):

- Severe acute allergic reaction (anaphylactic reaction).
- Inflammation of the liver (hepatitis) with yellowing of the skin and whites of the eyes (jaundice).
- Allergic reaction with skin rash and blisters formation.
- Joint pain/tenderness (polyarthritis).

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

- Inflammation of the colon (colitis caused by an infection with *Clostridium difficile*).
- Vaginal infection.
- Severe acute allergic reactions, such as significant drop in blood pressure, paleness, increased heart rate, clammy skin, reduced consciousness (anaphylactic shock, anaphylactoid reaction, hypersensitivity).
- Sleepiness.
- Dizziness.
- Headache.
- Jaundice.

- Fever, swollen lymphatic vessels or skin rashes, these symptoms indicate a DRESS syndrome (drug reaction with eosinophilia and systemic symptoms), which can be serious and life-threatening.
- A rare skin rash characterized by a rapid onset of skin redness with tiny pustules (small blisters saturated with white/yellow liquid) (Acute generalized exanthematous pustulosis – AGEP).
- Irritation at the site of injection.
- Fluid retention causing swelling in your legs, ankles or feet, shortness of breath or nausea.

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:

HPRA Pharmacovigilance
 Earlsfort Terrace
 IRL - Dublin 2
 Tel: +353 1 6764971
 Fax: +353 1 6762517
 Website: www.hpra.ie
 e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Clindamycin Villerton

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 bag, overpouch and carton. The expiry date refers to the last day of that month.

Do not store above 25 °C.

Do not use this medicine if you notice any discoloration, precipitation or any other particles.

Do not throw away any medicines 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 Clindamycin Villerton contains

- The active substance is clindamycin. Each ml contains 6 mg or 12 mg of clindamycin (as clindamycin phosphate). Each bag of 50 ml solution contains 300 mg or 600 mg of clindamycin (as clindamycin phosphate).
- The other ingredients are glucose monohydrate, disodium edetate, sodium hydroxide (for pH adjustment) and water for injections.

What Clindamycin Villerton looks like and contents of the pack

Clindamycin Villerton is a clear, colourless solution supplied in 100 ml transparent polyolefin bag equipped with two polyolefin tubing ports and a twist off port, containing 50 ml of sterile solution.

Pack sizes:

10 bags in foil overpouches

24 bags in foil overpouches

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Villerton Invest S.A.

14, Rue Edward Steichen

2540 Luxembourg

Manufacturer

Infomed Fluids Srl

Theodor Pallady Blv

Nr. 50, Sector 3,

Bucuresti, 032266

Romania

This medicinal product is authorised in the Member States of the EEA under the following names:

Norway:	Clindamycin Villerton 300 mg infusjonsvæske oppløsning Clindamycin Villerton 600 mg infusjonsvæske oppløsning
Denmark	Clindamycin Villerton 300 mg infusionsvæske opløsning Clindamycin Villerton 600 mg infusionsvæske opløsning
Sweden	Clindamycin Villerton Clindamycin Villerton
France	Clindamycine Villerton 300 mg solution pour perfusion Clindamycine Villerton 600 mg solution pour perfusion
Netherlands	Clindamycin Added Pharma 300 mg oplossing voor infusie Clindamycin Added Pharma 600 mg oplossing voor infusie
Finland	Clindamycin Villerton 300 mg infuusioneste liuos Clindamycin Villerton 600 mg infuusioneste liuos
Ireland	Clindamycin Villerton 300 mg solution for infusion Clindamycin Villerton 600 mg solution for infusion
United Kingdom	Clindamycin Villerton 300 mg solution for infusion Clindamycin Villerton 600 mg solution for infusion

This leaflet was last revised in 06/2022

The following information is intended for healthcare professionals only:

Only for single use. Any unused solution shall be discarded.

Do not use Clindamycin Villerton if you notice any particles or strong coloration of the solution. Only clear solutions free of visible particles should be used.

In the absence of compatibilities studies, this medicinal product must not be mixed with other medicinal products.

Solutions of clindamycin salts have a low pH and incompatibilities may reasonably be expected with alkaline preparations or drugs unstable at low pH.

Incompatibility has been reported with:

Ampicillin sodium, aminophylline, barbiturates, calcium gluconate, ceftriaxone sodium, ciprofloxacin, diphenylhydantoin, idarubicin hydrochloride, magnesium sulphate, phenytoin sodium, and ranitidine hydrochloride.

Do not store above 25 °C.