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**Package Leaflet:
Information for Healthcare Professionals**

Timentin® 3.2 g
ticarcillin and clavulanic acid

Dosage and Administration Information Only
Please refer to the Summary of Product Characteristics for further information

Presentation

Powder for solution for infusion.

Timentin 3.2 g: Vials of sterile powder providing 3.0 g ticarcillin with 200 mg clavulanic acid. The clavulanic acid is present as potassium clavulanate BP and the ticarcillin as ticarcillin sodium.

Contraindications

Timentin contains ticarcillin, which is a penicillin, and should not be given to patients with a history of hypersensitivity to beta-lactam antibiotics (e.g. penicillins and cephalosporins).

Posology and method of administration

Adult dosage (including elderly patients):

The usual dosage is 3.2 g Timentin given six to eight hourly. The maximum recommended dosage is 3.2 g four hourly.

Children's dosage (including infants, neonates and premature infants >2 kg in weight):

The usual dosage for children is 80 mg Timentin/kg body weight given every eight hours. The maximum dosage for children is 80 mg Timentin/kg body weight given every six hours. This should not be more than the maximum recommended dose for adults.

For premature infants <2 kg in weight, the dosage is 80 mg Timentin/kg body weight every 12 hours.

Renal impairment - Adults and children over 40 kg

An initial loading dose of 3 g should be followed by doses based on creatinine clearance rate and type of dialysis as indicated below:

- Creatinine clearance greater than 60 ml/minute: 3 g every 4 hours OR every 6 hours
- Creatinine clearance 30 to 60 ml/minute: 2 g every 4 hours OR 3g every 8 hours
- Creatinine clearance 10 to 30 ml/minute: 2 g every 8 hours OR 3 g every 12 hours
- Creatinine clearance less than 10 ml/minute: 1 g i.m. every 6 hours OR 2 g every 12 hours OR 3 g every 24 hours
- Creatinine clearance less than 10 ml/minute (with hepatic dysfunction): 1 g i.m. every 12 hours OR 2 g every 24 hours
- Patients on peritoneal dialysis: as for creatinine clearance less than 10 ml/minute
- Patients on haemodialysis: as for creatinine clearance less than 10 ml/minute supplemented with 3 g after each dialysis.

Renal impairment - Children under 40 kg

Similar dosage adjustment as for adults, e.g. an initial loading dose of 75 mg/kg should be followed by doses based on creatinine clearance and type of dialysis as indicated below:

- Greater than 30 ml/minute: 75 mg/kg every 8 hours
- 10 to 30 ml/minute: 37.5 mg/kg every 8 hours
- Less than 10 ml/minute: 37.5 mg/kg every 12 hours

NOTE: Each gram of Timentin contains approximately 11.9 mg of potassium and 100 mg of sodium.

Preparation and administration

Administration

Timentin is for administration by intermittent IV infusion. Timentin should be infused preferably in Water for Injections BP or Glucose Intravenous Infusion BP (5% or less).



**Package Leaflet:
Information for the Patient**

Timentin® 3.2 g
ticarcillin and clavulanic acid

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, nurse or pharmacist.
- 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, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1 What Timentin is and what it is used for

What Timentin is

Timentin 3.2 g (called 'Timentin' in this leaflet) is a penicillin antibiotic for intravenous (IV) infusion. It contains two different medicines, ticarcillin (present as ticarcillin sodium) and clavulanic acid (present as potassium clavulanate).

What Timentin is used for

Timentin is used to treat infections in different parts of the body caused by bacteria. Your doctor should test the type of bacteria causing your infection and monitor whether the bacteria are sensitive to Timentin during your treatment.

2 What you need to know before you have Timentin

Do not have Timentin if you:

- are allergic to ticarcillin, ticarcillin sodium, clavulanic acid, potassium clavulanate, penicillin or cephalosporin
- have ever had an allergic (hypersensitive) reaction to any antibiotic. This can include a skin rash or swelling of the face or neck
- have kidney or liver problems
- are on a restricted salt diet

Do not have Timentin if any of the above apply. If you are not sure, talk to your doctor, pharmacist or nurse before having Timentin.

Look out for important symptoms

Timentin can make some existing conditions worse, or cause serious side effects, such as allergic reactions, bleeding and severe diarrhoea (pseudomembranous colitis). You must look out for certain symptoms while you are receiving Timentin, to help reduce the risk of any problems. See section 4.

You may need regular tests

If you take Timentin for a long time, your doctor may arrange for you to have extra tests. These are to check your blood and to make sure your kidneys and liver are working properly.

Blood tests

If you are having any blood tests, let the doctor or nurse know that you are on Timentin. This is because Timentin can affect the results of these tests.

Other medicines and Timentin

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

Timentin should not be taken without first discussing this with your doctor if you are also taking:

- aminoglycoside-type antibiotics such as neomycin or gentamycin
- probenecid, a medicine for gout
- methotrexate, to treat cancer or rheumatic diseases.

Timentin may stop the contraceptive pill working. You will need to use extra contraceptive precautions, such as using a condom. If you need any advice, talk to your doctor or pharmacist.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine if you think you might be pregnant, if you are pregnant or if you are breast-feeding.

Important information about some of the ingredients of Timentin

- Timentin 3.2 g contains 320 mg of sodium per vial. This should be considered if you are on a controlled sodium diet.
- Timentin 3.2 g contains 39 mg of potassium per vial. This should be considered if you have kidney problems or are on a controlled potassium diet.

3 How Timentin is given

You will never give yourself this medicine. A qualified person, like a doctor or a nurse, will give you this medicine.

- The correct dose of Timentin will be decided by your doctor and depends on the type of infection, whether you are on any other antibiotics and your weight and age.
- Timentin will be given by a doctor or nurse into a vein by intravenous (IV) infusion. Timentin is made up by adding the following amount of Water for Injections or other suitable infusion fluid.

Vial size	Intravenous infusion (+Water for Injections)	Intravenous infusion (+Glucose IV infusion)
3.2 g	100 ml	100 to 150 ml

Further detailed instructions for the doctor or nurse are given in the section for the Healthcare Professional.

- Each dose will be infused over a period of 30 to 40 minutes. The usual doses are as follows.

Adults and elderly patients

3.2 g of Timentin given every 6 to 8 hours by IV infusion.

If you have a severe infection you may be prescribed 3.2 g every 4 hours.

Children (including premature babies weighing more than 2 kilograms)

80 mg of Timentin per kilogram of the child's body weight given every 8 hours by IV infusion.

The maximum dose for children is 80 mg Timentin per kilogram of the child's body weight given every 6 hours. This should not be more than the maximum recommended dose for adults.

Premature babies weighing less than 2 kilograms

80 mg of Timentin per kilogram of the child's body weight given every 12 hours by IV infusion.

Adults, elderly patients or children and babies with kidney problems

- may be given a different dose to the usual dose. The doctor or nurse will advise how much Timentin you will need, depending on the severity of the kidney disease
- your doctor will keep a close check on you and you may have more regular kidney function tests.

If you are on Timentin for a long time you should have blood tests to check your potassium levels.

Thrush (a yeast infection of moist areas of the body) may

develop if Timentin is used for a long time. If this occurs and you have been taking Timentin for longer than recommended, tell your doctor.

If you have too much Timentin

It is unlikely you will be given too much, but if you think you have been given too much Timentin, tell your doctor, pharmacist or nurse immediately. Signs might include feeling sick or being sick, diarrhoea or fits.

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

4 Possible side effects

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

Tell your doctor or nurse straight away if you notice any of the following serious side effects - you may need urgent medical treatment:

The following are rare (may affect up to 1 in 1,000 people)

- high temperature (fever), chills, a sore throat or other signs of an infection or if you bruise more easily. These may be signs of a problem with your blood cells
- inflammation of the large bowel (colon) with diarrhoea sometimes containing blood, pain and fever

The following are very rare (may affect up to 1 in 10,000 people)

- allergic reactions, the signs may include: skin itching or rash, swelling of the face, lips, tongue, body or breathing difficulties. These can be serious and occasionally deaths have occurred
- a skin reaction known as 'erythema multiforme' where you may develop: itchy reddish-purple patches on the skin especially on the palms of the hands or the soles of the feet, 'hive-like' raised swollen areas on the skin, tender areas of the surfaces of the mouth, eyes and private parts. You may have a fever and be very tired
- rash or pinpoint flat red round spots under the skin surface or bruising of the skin. This is due to inflammation of blood vessel walls due to an allergic reaction. It can be associated with joint pain (arthritis) and kidney problems
- other severe skin reactions can include: changes in skin colour, bumps under the skin, blistering, pustules, peeling, redness, pain, itch, scaling. These may be associated with fever, headaches and body aches
- changes to your white blood cells which might make you more susceptible to infections
- a decrease in the number of red blood cells in your blood, a symptom may be tiredness
- serious liver side effects may occur. You must tell your doctor urgently if you get:
 - severe diarrhoea with bleeding
 - blisters, redness or bruising of the skin
 - darker urine or paler stools
 - yellowing of the skin or the whites of the eyes (jaundice). See also anaemia below which might result in jaundice.
 These can happen when having the medicine or for up to several weeks after.
- an excessive breakdown of red blood cells causing a form of anaemia. Signs include: tiredness, headaches, shortness of breath, dizziness, looking pale and yellowing of the skin and the whites of the eyes

If any of the above happen to you speak to your doctor or nurse straight away as your medicine should be stopped.

Sometimes you may get less severe skin reactions such as:

- A mildly itchy rash (round, pink-red patches), 'hive-like' swollen areas on forearms, legs, palms, hands or feet. The frequency is unknown.

If you have this talk to your doctor or nurse as Timentin will need to be stopped.

The other possible side effects are:

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

- a lower than average amount of potassium in the blood
- inflammation of the bladder which may cause blood in your urine
- the blood may take longer to clot than it normally would. You may notice this if you have a nosebleed or cut yourself
- fits (convulsions) may be experienced in patients on high doses or with kidney problems

Frequency not known

- pain, burning, swelling or inflammation at the site of the injection
- skin rashes
- itching
- diarrhoea
- feeling sick (nausea)
- vomiting
- changes in the results of blood tests for liver function
- false positive red blood cell status tests (Coombs or rhesus test)

Reporting of side effects

If you notice 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

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

5 How to store Timentin

Timentin is for use in hospital only and the expiry date and storage instructions stated on the vial label and carton are for the doctor, nurse or pharmacist's information. The doctor, pharmacist or nurse will make up your medicine.

6 Contents of the pack and other information

What Timentin contains

- Timentin is available in one strength, 3.2 g. The active substance is 3 g of ticarcillin (present as ticarcillin sodium) and 200 mg of clavulanic acid (present as potassium clavulanate).
- There are no other ingredients. However, see section 2 for further important information about some of the ingredients of Timentin, sodium and potassium.

What Timentin looks like and contents of the pack

Timentin 3.2 g is supplied as sterile powder in glass vials with a rubber bung and aluminium seal. These are supplied to the hospital in packs of 4. Your doctor, pharmacist or nurse will make the IV infusion up with Water for Injections or a suitable infusion fluid. When made up, Timentin becomes a pale straw colour.

Marketing authorisation holder and manufacturer

Marketing Authorisation Holder: Laboratoires Delbert
49, rue Rouelle - 75015 Paris - France
Manufacturer: Biopharma S.r.l., Via delle Gerbere 22/30,
00134 Santa Palomba, Roma - Italy

Other formats

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name Timentin 3.2 g

Reference number 45352/0003

This is a service provided by the Royal National Institute of Blind People.

This leaflet was last revised in November 2021

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Reconstitution

Vials: The sterile powder should be dissolved in approximately 10 ml prior to dilution into the infusion container (e.g. mini-bag) or in-line burette. The following approximate infusion volumes are suggested:

	Water for Injections BP	Glucose Intravenous Infusion BP (5% w/v)
3.2 g	100 ml	100-150 ml

Each dose of Timentin should be infused intravenously over a period of 30-40 minutes; avoid continuous infusion over longer periods as this may result in subtherapeutic concentrations. 800 mg Timentin has a displacement value of 0.55 ml. Heat is generated when Timentin dissolves. Reconstituted solutions are normally a pale straw colour.

Timentin presentations are not for multi-dose use or for direct IV or IM injection. Any residual antibiotic solution should be discarded if less than the fully made up vial is used.

Stability and Compatibility

Timentin is stable in a range of intravenous fluids. Ideally, intravenous solutions should be prepared at the time of administration. However, Timentin infusions have been shown to be stable for the following extended periods; the infusion should be prepared under appropriate aseptic conditions and used within the times stated.

Intravenous fluids	Stability period (hours)	
	5°C	25°C
Water for Injections BP	72	24
Glucose Intravenous Infusion BP (5% w/v)	72	12
Sodium Chloride (0.18% w/v) and Glucose (4% w/v) Intravenous Infusion BP		24
Sodium Chloride Intravenous Infusion BP (0.9% w/v)		24
Dextran 40 Intravenous Infusion BP (10%) in Glucose Intravenous Infusion (5%)		6
Dextran 40 Intravenous Infusion BP (10%) in Sodium Chloride Intravenous Infusion (0.9%)		24
Glucose Intravenous Infusion BP (10% w/v)		6
Sorbitol Intravenous Infusion BP (30% w/v)		6
Sodium Lactate Intravenous Infusion BP (M/6)		12
Compound Sodium Lactate Intravenous Infusion BP (Ringer-Lactate Solution, Hartmann's Solution)		12

Incompatibilities

Timentin is not compatible with the following: Proteinaceous fluids (e.g. protein hydrolysates); blood and plasma; intravenous lipids; sodium bicarbonate. Timentin solutions containing lidocaine hydrochloride should not be used for intravenous administration.

If Timentin is prescribed concurrently with an aminoglycoside the antibiotics should not be mixed in the syringe, intravenous fluid container or giving set because loss of activity of the aminoglycoside can occur under these conditions.

Storage

Timentin vials should be stored in a dry place. Do not store above 25°C.

Marketing authorisation

PL 45352/0003

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