A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON 100 mg

1. NAME OF THE MEDICINAL PRODUCT

Pemetrexed Pfizer 100 mg powder for concentrate for solution for infusion
pemetrexed

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each vial contains 100 mg of pemetrexed (as pemetrexed ditromethamine)

After reconstitution, each vial contains 25 mg/ml of pemetrexed

3. LIST OF EXCIPIENTS

Contains mannitol

4. PHARMACEUTICAL FORM AND CONTENTS

Powder for concentrate for solution for infusion
100 mg
1 vial

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For intravenous use after reconstitution and dilution

Read the package leaflet before use.

Single use only

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

Cytotoxic

8. EXPIRY DATE

EXP
Read the package leaflet for the shelf life of the reconstituted product.

9. SPECIAL STORAGE CONDITIONS

Store below 30°C

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

Discard unused contents appropriately

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Pfizer Europe MA EEIG
Boulevard de la Plaine 17
1050 Bruxelles
Belgium

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/17/1183/001

13. BATCH NUMBER

BN

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Justification for not including Braille accepted

17. UNIQUE IDENTIFIER- 2D BARCODE

2D barcode carrying the unique identifier included

18. UNIQUE IDENTIFIER- HUMAN READABLE DATA

PC:
SN:
NN:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL LABEL 100 mg

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Pemetrexed Pfizer 100 mg powder for concentrate for solution for infusion
pemetrexed
IV

2. METHOD OF ADMINISTRATION

Reconstitute and dilute before use
See leaflet.

3. EXPIRY DATE

EXP

4. BATCH NUMBER

BN

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

100 mg

6. OTHER

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON 500 mg

1. NAME OF THE MEDICINAL PRODUCT

Pemetrexed Pfizer 500 mg powder for concentrate for solution for infusion
pemetrexed

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each vial contains 500 mg of pemetrexed (as pemetrexed ditromethamine)

After reconstitution each vial contains 25 mg/ml of pemetrexed

3. LIST OF EXCIPIENTS

Contains mannitol

4. PHARMACEUTICAL FORM AND CONTENTS

Powder for concentrate for solution for infusion
500 mg
1 vial

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For intravenous use after reconstitution and dilution

Read the package leaflet before use.

Single use only

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

Cytotoxic

8. EXPIRY DATE

EXP
Read the package leaflet for the shelf life of the reconstituted product.

9. SPECIAL STORAGE CONDITIONS

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

Discard unused contents appropriately

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Pfizer Europe MA EEIG
Boulevard de la Plaine 17
1050 Bruxelles
Belgium

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/17/1183/002

13. BATCH NUMBER

BN

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Justification for not including Braille accepted

17. UNIQUE IDENFIER- 2D BARCODE

2D barcode carrying the unique identifier included

18. UNIQUE IDENFIER- HUMAN READABLE DATA

PC:
SN:
NN:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL LABEL 500 mg

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Pemetrexed Pfizer 500 mg powder for concentrate for solution for infusion
pemetrexed
IV

2. METHOD OF ADMINISTRATION

Reconstitute and dilute before use
See leaflet.

3. EXPIRY DATE

EXP

4. BATCH NUMBER

BN

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

500 mg

6. OTHER

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON 1,000 mg

1. NAME OF THE MEDICINAL PRODUCT

Pemetrexed Pfizer 1,000 mg powder for concentrate for solution for infusion

pemetrexed

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each vial contains 1,000 mg of pemetrexed (as pemetrexed ditromethamine)

After reconstitution each vial contains 25 mg/ml of pemetrexed

3. LIST OF EXCIPIENTS

Contains mannitol

4. PHARMACEUTICAL FORM AND CONTENTS

Powder for concentrate for solution for infusion
1,000 mg
1 vial

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For intravenous use after reconstitution and dilution

Read the package leaflet before use.

Single use only

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

Cytotoxic

8. EXPIRY DATE

EXP
Read the package leaflet for the shelf life of the reconstituted product.

9. SPECIAL STORAGE CONDITIONS

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

Discard unused contents appropriately

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Pfizer Europe MA EEIG
Boulevard de la Plaine 17
1050 Bruxelles
Belgium

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/17/1183/003

13. BATCH NUMBER

BN

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Justification for not including Braille accepted

17. UNIQUE IDENFIER- 2D BARCODE

2D barcode carrying the unique identifier included

18. UNIQUE IDENFIER- HUMAN READABLE DATA

PC:
SN:
NN:

PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL LABEL 1,000 mg

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Pemetrexed Pfizer 1,000 mg powder for concentrate for solution for infusion
pemetrexed
IV

2. METHOD OF ADMINISTRATION

Reconstitute and dilute before use
See leaflet.

3. EXPIRY DATE

EXP

4. BATCH NUMBER

BN

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

1,000 mg

6. OTHER

B. PACKAGE LEAFLET

Package leaflet: Information for the user

Pemetrexed Pfizer 100 mg powder for concentrate for solution for infusion
Pemetrexed Pfizer 500 mg powder for concentrate for solution for infusion
Pemetrexed Pfizer 1,000 mg powder for concentrate for solution for infusion
pemetrexed

Read all of this leaflet carefully before you start receiving 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, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Pemetrexed Pfizer is and what it is used for

Pemetrexed Pfizer is a medicine used in the treatment of cancer.

Pemetrexed Pfizer is given in combination with cisplatin, another anti-cancer medicine, as treatment for malignant pleural mesothelioma, a form of cancer that affects the lining of the lung, to patients who have not received prior chemotherapy.

Pemetrexed Pfizer is also given in combination with cisplatin for the initial treatment of patients with advanced stage of lung cancer.

Pemetrexed Pfizer can be prescribed to you if you have lung cancer at an advanced stage if your disease has responded to treatment or it remains largely unchanged after initial chemotherapy.

Pemetrexed Pfizer is also a treatment for patients with advanced stage of lung cancer whose disease has progressed after other initial chemotherapy has been used.

2. What you need to know before you use Pemetrexed Pfizer

Do not use Pemetrexed Pfizer
- if you are allergic to pemetrexed or any of the other ingredients of this medicine (listed in section 6).
- if you are breast-feeding; you must discontinue breast-feeding during treatment with Pemetrexed Pfizer.
- if you have recently received or are about to receive a vaccine against yellow fever.

Warnings and precautions
Talk to your doctor or hospital pharmacist before receiving Pemetrexed Pfizer.

If you currently have or have previously had problems with your kidneys, talk to your doctor or hospital pharmacist as you may not be able to receive Pemetrexed Pfizer.

Before each infusion you will have samples of your blood taken to evaluate if you have sufficient kidney and liver function and to check that you have enough blood cells to receive Pemetrexed Pfizer. Your doctor may decide to change the dose or delay treating you depending on your general condition and if your blood cell counts are too low. If you are also receiving cisplatin, your doctor will make sure that you are properly hydrated and receive appropriate treatment before and after receiving cisplatin to prevent vomiting.

If you have had or are going to have radiation therapy, please tell your doctor, as there may be an early or late radiation reaction with Pemetrexed Pfizer.

If you have been recently vaccinated, please tell your doctor, as this can possibly cause bad effects with Pemetrexed Pfizer.

If you have heart disease or a history of heart disease, please tell your doctor.

If you have an accumulation of fluid around your lungs, your doctor may decide to remove the fluid before giving you Pemetrexed Pfizer.

Children and adolescents
There is no relevant use of pemetrexed in the paediatric population.

Other medicines and Pemetrexed Pfizer
Please tell your doctor if you are taking any medicine for pain or inflammation (swelling), such as medicines called “nonsteroidal anti-inflammatory drugs” (NSAIDs), including medicines purchased without a doctor’s prescription (such as ibuprofen). There are many sorts of NSAIDs with different durations of activity. Based on the planned date of your infusion of pemetrexed and/or on the status of your kidney function, your doctor needs to advise you on which medicines you can take and when you can take them. If you are unsure, ask your doctor or pharmacist if any of your medicines are NSAIDs.

Please tell your doctor or hospital pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy
If you are pregnant, think you may be pregnant or are planning to have a baby, tell your doctor. The use of pemetrexed should be avoided during pregnancy. Your doctor will discuss with you the potential risk of taking pemetrexed during pregnancy. Women must use effective contraception during treatment with pemetrexed.

Breast-feeding
If you are breast-feeding, tell your doctor. Breast-feeding must be discontinued during pemetrexed treatment.

Fertility
Men are advised not to father a child during and up to 6 months following treatment with pemetrexed and should therefore use effective contraception during treatment with pemetrexed and for up to 6 months afterwards. If you would like to father a child during the treatment or in the 6 months following receipt of treatment, seek advice from your doctor or pharmacist. You may want to seek counselling on sperm storage before starting your therapy.

Driving and using machines
Pemetrexed Pfizer may make you feel tired. Be careful when driving a car or using machines.

3. How to use Pemetrexed Pfizer

The dose of Pemetrexed Pfizer is 500 milligrams for every square metre of your body's surface area. Your height and weight are measured to work out the surface area of your body. Your doctor will use this body surface area to work out the right dose for you. This dose may be adjusted, or treatment may be delayed depending on your blood cell counts and on your general condition. A hospital pharmacist, nurse or doctor will have mixed the Pemetrexed Pfizer powder with water for injections and 5% glucose solution for injection before it is given to you.

You will always receive Pemetrexed Pfizer by infusion into one of your veins. The infusion will last approximately 10 minutes.

Use in combination with cisplatin
The doctor or hospital pharmacist will work out the dose you need based on your height and weight. Cisplatin is also given by infusion into one of your veins, and is given approximately 30 minutes after the infusion of Pemetrexed Pfizer has finished. The infusion of cisplatin will last approximately 2 hours.

You should usually receive your infusion once every 3 weeks.

Additional medicines
Corticosteriods: your doctor will prescribe you steroid tablets (equivalent to 4 milligram of dexamethasone twice a day) that you will need to take on the day before, on the day of, and the day after Pemetrexed Pfizer treatment. This medicine is given to you to reduce the frequency and severity of skin reactions that you may experience during your anticancer treatment.

Vitamin supplementation: your doctor will prescribe you oral folic acid (vitamin) or a multivitamin containing folic acid (350 to 1,000 micrograms) that you must take once a day while you are taking Pemetrexed Pfizer. You must take at least 5 doses during the seven days before the first dose of Pemetrexed Pfizer. You must continue taking the folic acid for 21 days after the last dose of Pemetrexed Pfizer. You will also receive an injection of vitamin B_{12} (1,000 micrograms) in the week before administration of Pemetrexed Pfizer and then approximately every 9 weeks (corresponding to 3 courses of Pemetrexed Pfizer treatment). Vitamin B_{12} and folic acid are given to you to reduce the possible toxic effects of the anticancer treatment.

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

4. Possible side effects

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

You must contact your doctor immediately if you notice any of the following:
- Fever or infection (common): if you have a temperature of 38ºC or greater, sweating or other signs of infection (since you might have less white blood cells than normal which is very common). Infection (sepsis) may be severe and could lead to death.
- If you start feeling chest pain (common) or having a fast heart rate (uncommon).
- If you have pain, redness, swelling or sores in your mouth (very common).
- Allergic reaction: if you develop skin rash (very common) / burning or prickling sensation (common), or fever (common). Rarely, skin reactions may be severe and could lead to death. Contact your doctor if you get a severe rash, or itching, or blistering (Stevens-Johnson syndrome or toxic epidermal necrolysis).
- If you experience tiredness, feeling faint, becoming easily breathless or if you look pale (since you might have less haemoglobin than normal which is very common).
- If you experience bleeding from the gums, nose or mouth or any bleeding that would not stop, reddish or pinkish urine, unexpected bruising (since you might have less platelets than normal which is very common).

- If you experience sudden breathlessness, intense chest pain or cough with bloody sputum (uncommon) (may indicate a blood clot in the blood vessels of the lungs).

Side effects with pemetrexed may include:

Very common (may affect more than 1 in 10 people)
Low white blood cells
Low haemoglobin level (anaemia)
Low platelet count
Diarrhoea
Vomiting
Pain, redness, swelling or sores in your mouth
Nausea
Loss of appetite
Fatigue (tiredness)
Skin rash
Hair loss
Constipation
Loss of sensation
Kidney: abnormal blood tests

Common (may affect up to 1 in 10 people)
Allergic reaction: skin rash / burning or prickling sensation
Infection including sepsis
Fever
Dehydration
Kidney failure
Irritation of the skin and itching
Chest pain
Muscle weakness
Conjunctivitis (inflamed eye)
Upset stomach
Pain in the abdomen
Taste change
Liver: abnormal blood tests
Watery eyes
Increased skin pigmentation

Uncommon (may affect up to 1 in 100 people)
Acute renal failure
Fast heart rate
Inflammation of the lining of the oesophagus (gullet) has been experienced with pemetrexed / radiation therapy.
Colitis (inflammation of the lining of the large bowel, which may be accompanied by intestinal or rectal bleeding)
Interstitial pneumonitis (scarring of the air sacs of the lung)
Oedema (excess fluid in body tissue, causing swelling). Some patients have experienced a heart attack, stroke or “mini-stroke” while receiving pemetrexed usually in combination with another anticancer therapy.
Pancytopenia- combined low counts of white cells, red cells and platelets
Radiation pneumonitis (scarring of the air sacs of the lung associated with radiation therapy) may occur in patients who are also treated with radiation either before, during or after their pemetrexed therapy.
Extremity pain, low temperature and discolouration have been reported.
Blood clots in the lung blood vessels (pulmonary embolism)

Rare (may affect up to 1 in 1,000 people)
Radiation recall (a skin rash like severe sunburn) which can occur on skin that has previously been exposed to radiotherapy, from days to years after the radiation.
Bullous conditions (blistering skin diseases)-including Stevens-Johnson syndrome and toxic epidermal necrolysis
Haemolytic anaemia (anaemia due to destruction of red blood cells)
Hepatitis (inflammation of the liver)
Anaphylactic shock (severe allergic reaction)

Not known: frequency cannot be estimated from the available data
Lower limb swelling with pain and redness
Increased urine output
Thirst and increased water consumption
Hypernatraemia – increased sodium in blood
Inflammation of the skin, mainly of the lower limb with swelling, pain and redness

Reporting of side effects
If you get any side effects, talk to your doctor. 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 Pemetrexed Pfizer

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

Pemetrexed Pfizer 100 mg powder for concentrate for solution for infusion
Store the 100 mg vial below 30°C.

Pemetrexed Pfizer 500 mg powder for concentrate for solution for infusion
The 500 mg vial does not require any special storage conditions.

Pemetrexed Pfizer 1,000 mg powder for concentrate for solution for infusion
The 1,000 mg vial does not require any special storage conditions.

Reconstituted and infusion solutions: When prepared as directed**,** chemical and physical in-use stability has been demonstrated for 24 hours at refrigerated temperature (2°C to 8°C) and at 25°C.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would not be longer than 24 hours at 2°C to 8°C.

The reconstituted solution is clear and ranges in colour from colourless to yellow or green-yellow without adversely affecting product quality. Parenteral medicines must be inspected visually for particulate matter and discolouration prior to administration. If particulate matter is observed, do not administer.

This medicine is for single use only; any unused solution must be disposed of in accordance with local requirement.

6. Contents of the pack and other information

What Pemetrexed Pfizer contains

The active substance is pemetrexed.

Pemetrexed Pfizer 100 mg powder for concentrate for solution for infusion
Each vial contains 100 milligrams of pemetrexed (as pemetrexed ditromethamine).

Pemetrexed Pfizer 500 mg powder for concentrate for solution for infusion
Each vial contains 500 milligrams of pemetrexed (as pemetrexed ditromethamine).

Pemetrexed Pfizer 1,000 mg powder for concentrate for solution for infusion
Each vial contains 1,000 milligrams of pemetrexed (as pemetrexed ditromethamine).

After reconstitution as directed, the solution contains 25 mg/ml of pemetrexed. Further dilution by a healthcare provider is required prior to administration.

The other ingredient is mannitol.

What Pemetrexed Pfizer looks like and contents of the pack

Pemetrexed Pfizer is a powder for concentrate for solution for infusion in a glass vial. It is a white to either light yellow or green-yellow lyophilised powder.

Each pack contains one glass vial of 100 mg, 500 mg or 1,000 mg pemetrexed.

Marketing Authorisation Holder

Pfizer Europe MA EEIG
Boulevard de la Plaine 17
1050 Bruxelles
Belgium

Manufacturer

Hospira UK Limited
Horizon
Honey Lane
Hurley
Maidenhead
SL6 6RJ
United Kingdom

Pfizer Service Company BVBA
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Belgium

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

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Pfizer Polska Sp. z o.o.
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PT
Laboratórios Pfizer, Lda.
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RO
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SI
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Pfizer, podružnica za svetovanje s področja farmacevtske dejavnosti, Ljubljana
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SK
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FI
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SE
Pfizer AB
Tel: +46 (0)8 550 520 00

LV
Pfizer Luxembourg SARL filiāle Latvijā
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UK
Hospira UK Ltd
Tel: + 44 (0) 1628 515500

This leaflet was last revised in month YYYY.

Other sources of information

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

This leaflet is available in all EU/EEA languages on the European Medicines Agency website.

The following information is intended for healthcare professionals only:

Instructions for use, handling and disposal

1. Use aseptic technique during the reconstitution and further dilution of pemetrexed for intravenous infusion administration.

2. Calculate the dose and the number of Pemetrexed Pfizer vials needed. Each vial contains an excess of pemetrexed to facilitate delivery of label amount.

3. Pemetrexed Pfizer must only be reconstituted with sterile water for injections.

Pemetrexed Pfizer 100mg vial:
Reconstitute each 100 mg vial with 4.2 ml of sterile water for injections, resulting in a solution containing 25 mg/ml pemetrexed.

Pemetrexed Pfizer 500mg vial:
Reconstitute each 500 mg vial with 20 ml of sterile water for injections, resulting in a solution containing 25 mg/ml pemetrexed.

Pemetrexed Pfizer 1,000mg vial:
Reconstitute each 1,000 mg vial with 40 ml of sterile water for injections, resulting in a solution containing 25 mg/ml pemetrexed.

Gently swirl each vial until the powder is completely dissolved. The resulting solution is clear and ranges in colour from colourless to yellow or green-yellow without adversely affecting product quality. The pH of the reconstituted solution is between 5.7 and 7.7. **Further dilution is required.**

4. Pemetrexed Pfizer must only be further diluted with 5% glucose solution, without preservative. The appropriate volume of reconstituted pemetrexed solution must be further diluted to 100 ml with 5% glucose solution for injection, without preservative, and administered as an intravenous infusion over 10 minutes.

5. Pemetrexed infusion solutions prepared as directed above are compatible with polyvinyl chloride- and polyolefin- lined administration sets and infusion bags. Pemetrexed is incompatible with diluents containing calcium, including lactated Ringer's Injection and Ringer's Injection

6. Parenteral medicinal products must be inspected visually for particulate matter and discolouration prior to administration. If particulate matter is observed, do not administer.

7. Pemetrexed solutions are for single use only.

Any unused medicinal product or waste material must be disposed of in accordance with local requirements.

Preparation and administration precautions: As with other potentially toxic anti-cancer agents, care should be exercised in the handling and preparation of pemetrexed infusion solutions. The use of gloves is recommended. If a pemetrexed solution contacts the skin, wash the skin immediately and thoroughly with soap and water. If pemetrexed solutions contact the mucous membranes, flush thoroughly with water. Pemetrexed is not a vesicant. There is not a specific antidote for extravasation of pemetrexed. There have been few reported cases of pemetrexed extravasation, which were not assessed as serious by the investigator. Extravasation should be managed by local standard practice as with other non-vesicants.