

FINAL PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

PEMETREXED SOLUTION 100 mg/4 ml ACCORD
PEMETREXED SOLUTION 500 mg/20 ml ACCORD
PEMETREXED SOLUTION 850 mg/34 ml ACCORD
PEMETREXED SOLUTION 1000 mg/40 ml ACCORD

Solution for infusion

Pemetrexed disodium (hemipentahydrate)

Read all of this leaflet carefully before you are given PEMETREXED SOLUTION

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.

What is in this leaflet:

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

1. What PEMETREXED SOLUTION is and what it is used for

PEMETREXED SOLUTION is a medicine used in the treatment of cancer.

- **Malignant pleural mesothelioma:** This is a cancer which affects the inside lining of the chest cavity. **PEMETREXED SOLUTION** is given with cisplatin, another anti-cancer medicine.
- **PEMETREXED SOLUTION** is also used for the advanced stage of lung cancer (of a certain type called non-small cell type) after other chemotherapy has been used.

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PEMETREXED SOLUTION inhibits the growth of the tumour cells and may reduce tumour size.

2. What you need to know before you use PEMETREXED SOLUTION

PEMETREXED SOLUTION should not be administered to you:

- if you are hypersensitive (allergic) to pemetrexed or any of the other ingredients of **PEMETREXED SOLUTION** (listed in section 6).
- if you are breastfeeding your baby
- in combination with a vaccine called yellow fever vaccine

Warnings and precautions

Tell your doctor or healthcare professional before being given the injection:

Special care should be taken with **PEMETREXED SOLUTION**:

- Treatment with **PEMETREXED SOLUTION** can reduce the number of white blood cells produced by your bone marrow and you will therefore be more prone to infections. During treatment, you will have regular blood tests to check your number of white blood cells. Occasionally, treatment may need to be delayed if your blood cell count is too low. The results from the blood tests will also assist your doctor in determining the dose of **PEMETREXED SOLUTION** for your next treatment.
- To reduce the chances of side effects; you must take folic acid and vitamin B₁₂ before and during treatment with **PEMETREXED SOLUTION**.
- To reduce the chances of skin reactions; you will be given a corticosteroid tablet to take before and during treatment with **PEMETREXED SOLUTION**.
- Tell your doctor or pharmacist if you are taking medicines called non-steroidal
- anti-inflammatory medicines (NSAIDs) for pain or swelling. Depending on the health of your kidneys or the type of NSAID you are taking; you may need to discontinue the use of this medicine for a period of time before and after treatment with **PEMETREXED SOLUTION**.

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- If the blood test results show that your kidneys are not functioning well, then you may need to stop treatment with **PEMETREXED SOLUTION**.
- If you have a large amount of fluid build-up in the stomach, lungs or chest cavity; then the fluid may need to be drained before starting your treatment with **PEMETREXED SOLUTION**.
- Your ability to fall pregnant or father a child may be affected by having cancer treatment. It's important to discuss fertility with your doctor before starting your treatment with **PEMETREXED SOLUTION**. It is not advisable to fall pregnant or father a child whilst being treated with **PEMETREXED SOLUTION** and for 6 months afterwards; as it may harm the developing baby.
- Do not have any immunisations (vaccinations) without your doctor's approval whilst being treated with **PEMETREXED SOLUTION**. Cancer therapy may lower your body's resistance to infections and there is a chance you might get the infection the immunisation is meant to prevent.
- 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 SOLUTION**.

Children and adolescents

The safety and effectiveness of **PEMETREXED SOLUTION** in patients under the age of 18 has not yet been determined, therefore the use of this anti-cancer medicine is not recommended.

Other medicines and PEMETREXED SOLUTION

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

PEMETREXED SOLUTION can interfere with some other medicines such as:

- Aminoglycosides and penicillin; antibiotics used to treat infections.
- Certain diuretics; used to treat high blood pressure or the retention of fluids in the body.
- Cyclosporin; used to suppress immunity in transplant patients.

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- Non-steroidal anti-inflammatories (such as ibuprofen, piroxicam or rofecoxib); used to treat pain or swelling.

Pregnancy, breastfeeding and fertility

Pregnancy:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before being given **PEMETREXED SOLUTION**. **PEMETREXED SOLUTION** may harm the unborn baby and should be avoided during pregnancy. Women should avoid falling pregnant during treatment with **PEMETREXED SOLUTION**.

Breast-feeding:

It is not known whether **PEMETREXED SOLUTION** passes into breast milk. Breastfeeding should stop once treatment with **PEMETREXED SOLUTION** is started.

Fertility:

Men are advised not to father a child during and up to 6 months following treatment with **PEMETREXED SOLUTION** and should therefore use effective contraception during treatment with **PEMETREXED SOLUTION** 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

As **PEMETREXED SOLUTION** may cause tiredness, you are advised not to drive or operate machinery.

It is not always possible to predict to what extent **PEMETREXED SOLUTION** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **PEMETREXED SOLUTION** affects them.

PEMETREXED SOLUTION contains sodium.

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PEMETREXED SOLUTION contains 8.44 mg of sodium per ml of solution. To be taken into consideration by patients on a controlled sodium diet.

3. How to use PEMETREXED SOLUTION

PEMETREXED SOLUTION will be administered by a doctor or healthcare professional in a hospital setting, where emergency equipment is available.

Your doctor will calculate the right dose according to your specific disease.

The duration of treatment depends on your disease and response to treatment.

PEMETREXED SOLUTION will be administered into a vein slowly over a longer period of time, either alone or in combination with other medicines.

You will have regular blood tests before and during your treatment with **PEMETREXED SOLUTION**. Your doctor may adjust your dose of **PEMETREXED SOLUTION** or delay treatment based on the results of your blood tests and on your general condition.

If you were administered more PEMETREXED SOLUTION than you should

Since a healthcare professional will administer **PEMETREXED SOLUTION** he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use PEMETREXED SOLUTION

Since a healthcare professional will administer **PEMETREXED SOLUTION**, it is unlikely that the dose will be missed.

If you stop using PEMETREXED SOLUTION

If you interrupt your treatment with **PEMETREXED SOLUTION** your symptoms may come back.

Therefore, do not stop using **PEMETREXED SOLUTION** unless your doctor tells you to.

If you have any further questions on the use of **PEMETREXED SOLUTION**, ask your doctor, pharmacist or nurse.

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4. Possible side effects

PEMETREXED SOLUTION can have side effects.

Not all side effects reported for **PEMETREXED SOLUTION** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while being treated with **PEMETREXED SOLUTION**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop using PEMETREXED SOLUTION and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Fever or infection: if you have a temperature of 38 °C 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 or having a fast heart rate.
- If you experience sudden breathlessness, intense chest pain or cough with bloody sputum (may indicate a blood clot in the blood vessels of the lungs).

These are all very serious side effects. If you have them, you may have had a serious reaction to **PEMETREXED SOLUTION**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- 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).
- 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).
- If you have pain, redness, swelling or sores in your mouth.

Applicant/HCR: Accord Healthcare (Pty) Ltd
Pemetrexed Solution 100 mg/4 ml; 500 mg/20 ml; 850 mg/34 ml; 1000 mg/40 ml Accord
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- Allergic reaction: if you develop skin rash / burning or prickling sensation, or fever. Skin reactions may be severe and could lead to death.

Tell your doctor if you notice any of the following:

Frequent

- Low white blood cells (repeated fever, chills and infections)
- Low haemoglobin level (anaemia) (feeling weak, tired, looking pale, shortness of breath, increase in heart rate)
- Low platelet count (unexpected bruising, bleeding from nose, gums or mouth)
- 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
- 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

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- Conjunctivitis (inflamed eye)
- Upset stomach
- Pain in the abdomen
- Taste change
- Liver: abnormal blood tests
- Watery eyes
- Increased skin pigmentation

Less frequent

- Acute renal failure
- Fast heart rate
- 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 SOLUTION** usually in combination with another anticancer therapy.
- Pancytopenia- combined low counts of white cells, red cells and platelets.
- Extremity pain, low temperature and discolouration have been reported.
- Blood clots in the lung blood vessels (pulmonary embolism).
- 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.
- Immune mediated haemolytic anaemia (antibody-mediated destruction of red blood cells).
- Hepatitis (inflammation of the liver).
- Anaphylactic shock (severe allergic reaction)

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Frequency not known:

- 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

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get 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 to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of **PEMETREXED SOLUTION**.

5. How to store PEMETREXED SOLUTION

- Store all medicines out of reach and sight of children.
- Store at or below 25 °C.
- Keep the vial in the outer carton until required for use.
- Protect from light. Do not use **PEMETREXED SOLUTION** if you notice particles or a change of colour.
- Do not use this medicine after the expiry date which is stated on the carton and the vial after “EXP”.
- The expiry date refers to the last day of that month. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

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What PEMETREXED SOLUTION contains

- The active substance is pemetrexed (as pemetrexed disodium hemipentahydrate).
- Each ml of solution contains 25 mg of Pemetrexed (as pemetrexed disodium hemipentahydrate).
- Each vial of 4 ml of solution contains 100 mg of Pemetrexed (as pemetrexed disodium hemipentahydrate).
- Each vial of 20 ml of solution contains 500 mg of Pemetrexed (as pemetrexed disodium hemipentahydrate).
- Each vial of 34 ml of solution contains 850 mg of Pemetrexed (as pemetrexed disodium hemipentahydrate).
- Each vial of 40 ml of solution contains 1000 mg of Pemetrexed (as pemetrexed disodium hemipentahydrate).
- The other ingredients are citric acid, L-Methionine, Monothioglycerol, water for injections.

What PEMETREXED SOLUTION looks like and contents of the pack

- **PEMETREXED SOLUTION** is a clear, colourless to pale yellow solution in a clear, glass vial.
- Each pack of **PEMETREXED SOLUTION** consists of one vial.

Holder of Certificate of Registration

Accord Healthcare (Pty) Ltd
Building 2, Tuscany Office Park,
6 Coombe Place,
Rivonia
Gauteng,
South Africa

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Email address: medinfo@accordhealth.co.za

This leaflet was last revised in

To be allocated by the Authority

Registration Numbers

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