Show this card to any doctors or medical personnel involved in your treatment, not just your neurologist.

Please read the package insert for mitoxantrone (active ingredient: mitoxantrone) carefully before using this medication.

It is very important to perform tests both during the treatment and for up to 5 years after the last dose (even if you are feeling well).

Carry this card for 5 years after the last dose mitoxantrone, as side effects can still occur months or even years after ending treatment with mitoxantrone; tell your doctor about this also.

Reporting of Adverse Events

If you notice side effects, contact your doctor or pharmacist. You may also report suspected adverse reactions directly to the Health Products Regulatory Authority (HPRA) at:
HPRA
Pharmacovigilance,
Website: www.hpra.ie

Any suspected adverse reactions may also be reported to Pfizer Medical Information on 1800 633 363.

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

Name of the patient:

Start date of mitoxantrone therapy:

End date of mitoxantrone therapy:

Name of the prescribing physician:

Telephone number of the prescribing physician:

Mitoxantrone

Mitoxantrone

Patient Alert Card

Essential information on risk minimisation

Mitoxantrone 2 mg/ml concentrate for solution for infusion

PP-ONC-IRL- 0274
Date of preparation: May 2020

Mitoxantrone

For the treatment of patients with highly active relapsing multiple sclerosis (MS) with rapidly progressing disability where no alternative therapeutic options exist

This Alert Card contains important safety information that you must be aware of before, during and after the treatment with mitoxantrone.

Like all medications, this medication causes side effects but not every patient gets them. The most serious side effects are:

1. Heart failure

Mitoxantrone can damage your heart and cause your heart function to worsen culminating in its severest form, heart failure.

Signs and symptoms include:

- Shortness of breath
- Fluid accumulation (swelling) in the ankles and legs
- Changes in heartbeat rate (fast or slow)
- Fatigue
- Decreased ability for physical activity

This may occur either during or even months or years after treatment with mitoxantrone. Your doctor will check your heart function before starting treatment, before each subsequent dose and annually for up to 5 years after ending treatment

2. Acute myeloid leukaemia (AML) and myelodysplastic syndrome (MDS)

Mitoxantrone can cause the following conditions when taken alone or in combination with other cancer medications and/or radiotherapy:

- Cancer of the white blood cells (AML)
- A disease of the bone marrow that causes abnormal shaped blood cells and leads to leukaemia (MDS)

Many signs and symptoms of AML result from a decrease in normal blood cells, both white and red blood cells and platelets.

Signs and symptoms include:

- Fever or infections (signs of a low white blood cell count)
- If your skin becomes pale and you feel week or suffer sudden respiratory distress (possible signs of a low red blood cell count)
- Unusual blue spots or bleeding, such as coughing up blood, blood in vomit or in urine or black stool (possible signs of low platelet count)

These can still occur months or even years after ending your treatment with mitoxantrone.

Tell your doctor, pharmacist or carer immediately if you notice any of the above signs or symptoms (heart failure or AML or MDS) during or after treatment with mitoxantrone.

Further information can be found in the Package Leaflet for mitoxantrone and on the website: www.medicines.ie