PROPOSED PATIENT INFORMATION LEAFLET (FINAL)

24 OCTOBER 2011

Please read this leaflet carefully before you are given **MYLAN IRINOTECAN.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **MYLAN IRINOTECAN** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1) SCHEDULING STATUS:

S4

2) PROPRIETARY NAMES AND DOSAGE FORM:

MYLAN IRINOTECAN 40 mg/2 ml (concentrate for solution for infusion)

MYLAN IRINOTECAN 100 mg/5 ml (concentrate for solution for infusion)

3) WHAT MYLAN IRINOTECAN CONTAINS:

MYLAN IRINOTECAN 40 mg/2 ml: Each single-dose 4 ml vial contains 40 mg irinotecan hydrochloride trihydrate per 2 ml (40 mg/2 ml)

This product also contains: sorbitol, lactic acid, sodium hydroxide and water for injection

MYLAN IRINOTECAN 100 mg/5 ml: Each single-dose 10 ml vial contains 100 mg irinotecan hydrochloride trihydrate per 5 ml (100 mg/5 ml)

This product also contains: sorbitol, lactic acid, sodium hydroxide and water for injection

4) WHAT MYLAN IRINOTECAN IS USED FOR:

MYLAN IRINOTECAN belongs to a group of medicines called cytostatics (anti-cancer medicines).

MYLAN IRINOTECAN is used for the treatment of advanced cancer of the colon and rectum in adults, either in a combination with other medicines or alone.

5) BEFORE YOU RECEIVE MYLAN IRINOTECAN:

Do not receive MYLAN IRINOTECAN:

- If you are hypersensitive (allergic) to irinotecan or to any of the other ingredients in **MYLAN IRINOTECAN**.

- If you have any other bowel disease or a history of bowel obstruction. Treatment with **MYLAN IRINOTECAN** must only be started after you have received treatment for this.

- If you have or develop severe bone marrow depression or failure.

- If you have certain blood disorders (If you have increased levels of bilirubin in the blood (more than 1,5 times the upper limit of normal)

- If you are in poor general health.

- If you are using the product St John's Wort (*Hypericum perforatum)* as it may decrease the effect of **MYLAN IRINOTECAN**.

- If you are pregnant or breast-feeding.

- **MYLAN IRINOTECAN** is intended for adults only.

Take special care with MYLAN IRINOTECAN:

Problems with liver and kidney function:

If you have liver and/or kidney problems, special care will be taken by your doctor when he is considering to treat you with **MYLAN IRINOTECAN**.

Diarrhoea:

During receiving treatment with **MYLAN IRINOTECAN** and shortly after receiving treatment you may experience diarrhoea. The diarrhoea may start more than 24 hours after receiving treatment but it may also start a few days later. Your doctor will treat the diarrhoea immediately and keep you under close supervision.

Do not take any treatment for the diarrhoea other than that given to you by your doctor and the fluids described.

If you develop any fever contact your doctor or the unit immediately so that they can give you any treatment necessary.

Neutropenia:

MYLAN IRINOTECAN can cause a decrease in the number of some of your white blood cells, which play an important role in fighting infections. This is called

neutropenia. Neutropenia is sometimes seen during treatment with **MYLAN IRINOTECAN** and is reversible.

Your doctor will arrange for you to have regular blood tests to monitor these white blood cells. Neutropenia is serious and should be treated immediately and carefully monitored.

Breathing difficulties:

If you have any breathing difficulties contact your doctor immediately.

Liver:

Before treatment with **MYLAN IRINOTECAN** is started and before every following treatment cycle your doctor will check your liver function (by blood tests).

Nausea and vomiting:

If you have nausea and/or vomiting contact your doctor or the unit immediately.

Acute cholinergic syndrome:

Acute cholinergic syndrome is the medical term for some of the symptoms that you may experience such as: diarrhoea, sweating, abdominal pain, watering eyes, visual disturbance, excessive mouth watering. If you have any of these symptoms immediately tell your doctor who will give you any treatment necessary.

Elderly:

If you are an elderly patient, the dosage of **MYLAN IRINOTECAN** will be carefully monitored because of the possibility that your kidney, liver or heart functions may be decreased.

Immunisation:

You must avoid immunisation unless this is approved by your doctor.

Risk-benefits which will be considered by your doctor:

Your doctor will consider whether it is suitable for you to receive **MYLAN IRINOTECAN** in the following medical conditions:

- chickenpox (if you have or recently had)
- certain viral infections
- infections as this could delay your recovery
- bone marrow depression
- decreased liver function
- heart disease or decreased heart function
- if you had any previous treatment or radiation therapy

If you have one or more of the symptoms mentioned above, after you have returned home from the hospital, you should immediately contact the doctor or the hospital department supervising your treatment.

Pregnancy and Breast-feeding:

You must not be given **MYLAN IRINOTECAN** if you are pregnant or breast-feeding.

Your doctor will tell you what effect **MYLAN IRINOTECAN** could have on the baby if you received it during pregnancy or if you become pregnant while receiving treatment.

Safety and efficacy of **MYLAN IRINOTECAN** have not been established in children.

During receiving treatment with **MYLAN IRINOTECAN** and for at least three months afterwards you must use birth control measures.

If you are pregnant or breast-feeding your baby while receiving MYLAN IRINOTECAN, please consult your doctor, pharmacist or other health care professional for advice.

Driving or using machinery:

MYLAN IRINOTECAN may make you feel dizzy or cause visual disturbances. If this happens to you, do not drive or use machinery.

Important information about some of the ingredients of MYLAN IRINOTECAN:

MYLAN IRINOTECAN contains sorbitol. If you suffer from an **intolerance to some sugars,** tell your doctor before you are given **MYLAN IRINOTECAN.**

Taking other medicines with MYLAN IRINOTECAN:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of MYLAN IRINOTECAN with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

Some medicines may change the effects of **MYLAN IRINOTECAN**.

You should not receive anaesthetic medicines such as suxamethonium while you are receiving treatment with **MYLAN IRINOTECAN** as it will change the way that these medicines work.

Also, if you must have an operation, please tell your doctor or anaesthetist that you are receiving **MYLAN IRINOTECAN**, as it may alter the effect of some medicines used during surgery.

You must not receive the medicine loperamide, which is used to treat diarrhoea, before starting your treatment with **MYLAN IRINOTECAN.**

You should not use the herbal medicine St John's Wort (*Hypericum perforatum)* while you are receiving **MYLAN IRINOTECAN** and between treatments, as it may decrease the effect of **MYLAN IRINOTECAN**.

6) HOW WILL YOU BE GIVEN MYLAN IRINOTECAN:

As **MYLAN IRINOTECAN** is an anti-cancer medicine it will be administered to you in a special unit and under supervision of a doctor qualified in the use of anti-cancer medicines.

Your doctor will decide on the dosage that is appropriate for you. These dosages may be adjusted by your doctor depending on your condition and any side effects you may have.

If you are given more MYLAN IRINOTECAN than you should:

Your doctor will take appropriate actions immediately.

If you have more questions on the use of **MYLAN IRINOTECAN**, please ask your doctor or pharmacist.

7) POSSIBLE SIDE EFFECTS:

MYLAN IRINOTECAN can cause side effects. Your doctor will discuss the side effects with you and explain the risks and benefits of your treatment.

The following less frequent side effect must be treated immediately:

- Breathing difficulties (possible symptom of severe allergic reactions)

Frequent side effects include:

- Blood disorders which include too few white blood cells; too few blood platelets; decreased number of red blood cells; inflammation of a vein with formation of a clot; blood clot.
- Headache; inability to sleep; sleepiness; dizziness.
- Various heart disorders which include irregularity of heart beat; low blood pressure; inadequate blood supply/oxygen to heart muscle; heart attack.
- Shortness of breath; cough.
- Nausea, vomiting, diarrhoea, possibly preceded by stomach cramps and/or sweating; stomach enlargement, cramps and pain; weight loss; constipation; other stomach disorders (heartburn, excess of air/gas in the stomach, mucous membrane problems, inflammation of the mouth).
- Liver disorders which include yellow pigmentation of skin and eyes.
- Skin rash; redness and/or swelling of palms of hands and bottoms of feet, as well as blistering and peeling; hair loss.
- Back pain; lack of energy; pins and needles.
- Swelling due to retained fluid.

- Fainting; fever; chills.

Less frequent side effects include:

- Bleeding disorder; fever associated with too few blood cells.
- Confusion; lack of well-being.
- Flushing due to widening of the blood vessels.
- Lung infection; runny nose.
- Blocking of the intestine; paralysis of the intestines or gastro-intestinal bleeding; perforation of the intestines.
- Inflammation of the colon.
- Muscle contraction; cramps.
- Kidney disorders or acute kidney failure.
- "Severe transient acute cholinergic syndrome": this is the medical term for symptoms such as abdominal pain; red, sore, itching or weeping eyes; sweating; chills; visual disturbances; watering eyes and excessive watering of mouth.

In laboratory tests there could be changes in blood test results.

Not all side effects reported for **MYLAN IRINOTECAN** are included in this leaflet. Should your general health worsen while receiving **MYLAN IRINOTECAN**, please tell your doctor, pharmacist or other health care professional.

8) STORAGE AND DISPOSAL OF MYLAN IRINOTECAN:

Keep in the carton until required for use.

Single-dose vials of **MYLAN IRINOTECAN** should be stored at or below 25 °C and protected from light.

After dilution in either 0,9 % sodium chloride or 5 % glucose, the diluted solution is stable for 6 hours at a temperature at or below 25 °C or 24 hours under refrigeration (2 - 8 °C) protected from light.

Discard any unused portion thereafter.

Do not freeze.

KEEP **MYLAN IRINOTECAN** OUT OF THE REACH OF CHILDREN

Medicines must not be used after the expiry date stated on the label.

Return all unused medicines to your pharmacist.

Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).

9) PRESENTATION OF MYLAN IRINOTECAN:

MYLAN IRINOTECAN 40 mg/2 ml: Carton contains an amber coloured Type I Ph

MYLAN IRINOTECAN 40 mg/2 ml: Carton containing an amber coloured Type I Ph Eur glass vial with a nominal volume of 4 ml, a 13 mm dark grey chlorobutyl rubber stopper and a 13 mm red aluminium flip-off seal.

MYLAN IRINOTECAN 100 mg/5 ml: Carton containing an amber coloured Type I Ph Eur glass vial with a nominal volume of 10 ml, a 20 mm dark grey chlorobutyl rubber stopper and a 20 mm yellow aluminium flip-off seal.

1, 5, 10 or 20 vials are packed in a cardboard carton. Not all pack sizes may be marketed.

10) IDENTIFICATION OF MYLAN IRINOTECAN:

Amber coloured vials containing a clear, sterile, pale yellow solution and packaged into an outer carton.

11) REGISTRATION NUMBERS:

MYLAN IRINOTECAN 40 mg/2 ml: 43/26/0349

MYLAN IRINOTECAN 100 mg/5 ml: 43/26/0348

12) NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE:

XIXIA PHARMACEUTICALS (PTY) LTD

Building 6, Greenstone Hill Office Park

Emerald Boulevard

MODDERFONTEIN, 1645

12) DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

24 October 2011