



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Corporate Pharmaceutical Unit
Health Service Executive
Dr. Steevens' Hospital
Dublin 8

Tel: (01) 635 2672
Fax: (01) 635 2358
E-mail: CPU@HSE.IE

7th January 2011

Important Communication: Shelf Life Extension

Tamiflu 75mg Hard Capsule, EU/1/02/222/001

Batch number	Date of Manufacture	Original Expiry Date	Final New Expiry Date
B1140	07.06.2005	30-Jun-10	30-Jun-12
B1145	11.07.2005	31-Jul-10	31-Jul-12
B1156	05.08.2005	31-Aug-10	31-Aug-12

Dear Pharmacist,

Further to our communication with you of the 9th of July 2010 in relation to the expiry date of Tamiflu Capsules, we wish to provide you with the following information.

As communicated previously, on the 14th September 2009, the European Medicines Agency (EMA) approved an extension to the shelf life of Oseltamivir (Tamiflu®) capsules from 5 years to 7 years where they have always been stored at below 25°C.

A number of batches of Oseltamivir (Tamiflu®) capsules supplied to you via the HSE have passed the expiry date which was placed on the pack at the time of manufacture. However, the decision of the EMA means that these medicines should not be discarded as the expiry date has now been extended.

The MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) REGULATIONS 2009 (S.I. No. 442 of 2009) amended the provision regarding the offence of supplying a medicinal product after its expiry date to take account of circumstances where the body which has authorised the placing of the product on the market has determined that the expiry date may be extended.

Please find above the original date of manufacture, the batch number, the original expiry date placed on the carton at the time of manufacture and the new expiry date for affected batches of Tamiflu 75mg Capsules.

Packs of these batches of Tamiflu are safe to use until they reach the new updated expiry date listed above, provided they have been stored below 25°C.

With this communication, we are providing you with an information leaflet for provision to patients. This leaflet explains the expiry date issue for patients. A copy of the information leaflet should be provided to each patient who is

dispensed a pack of any of the above batches. Copies of this leaflet are available for download from: www.hse.ie/eng/services/swineflu

If you have any queries relating to either communication please contact the HSE Corporate Pharmaceutical Unit @ 01 6352672 (cpu@hse.ie).

Yours Sincerely



Shaun Flanagan MPSI

Tamiflu Capsules– Important Information for Patients

What is Tamiflu and what is it used for?

Tamiflu is prescribed to you for treating or preventing flu or influenza virus. It is an anti-viral medicine. These medicines prevent the flu virus from spreading inside your body. They help to ease or prevent flu symptoms.

What does an Expiry Date mean?

When a medicine is manufactured, the manufacturer must place an expiry date on the package. Manufacturers must have enough information and scientific evidence to guarantee the full strength and safety of the medicine until the expiry date. This information is checked by the Irish Medicines Board and the European Medicines Agency, who make sure that medicines are safe, effective and of high quality. Until 2009, the information available only guaranteed the strength and safety of Tamiflu for 5 years

Why does my Tamiflu appear to have passed its expiry date?

In 2009, detailed scientific information became available, which guaranteed the full strength and safety of Tamiflu for an extra 2 years beyond the labelled five year expiry date. This means that packs of Tamiflu which were originally labelled with an expiry date of 5 years from the date of manufacture are safe to use for an extra two years, provided they have been stored below 25 degrees Celsius.

Your Health Care Professional has checked the batch which has been given to you and has confirmed that it is within its revised 7 year shelf life. Please be assured that the pack is safe to use.

From:

HSE Corporate Pharmaceutical Unit, Dr. Steevens' Hospital, Dublin 8

Telephone : 01 6352672 Email contact: cpu@hse.ie www.hse.ie