NARCOLEPSY

FREQUENTLY ASKED QUESTIONS

Anyone with concerns about narcolepsy should speak to their GP.

What is narcolepsy?

Narcolepsy is a sleep disorder that causes overwhelming and severe daytime sleepiness. People with narcolepsy fall asleep at inappropriate times and places. These daytime sleep attacks may occur with or without warning, and can occur repeatedly in a single day.

What are the main symptoms of narcolepsy?

Narcolepsy is typically characterized by the following four symptoms with varying frequencies:

(i) Excessive daytime sleepiness,
(ii) Cataplexy (sudden and temporary loss of muscle tone often triggered by emotions such as laughter),
(iii) Hallucinations (intense, vivid and sometimes terrifying hallucinations at the beginning and ending of a sleep period),
(iv) Sleep paralysis (paralysis that occurs most often upon falling asleep or waking up; the person is unable to move for a few minutes).

How common is narcolepsy?

International evidence indicates that around one in 100,000 people per year develop narcolepsy. According to the Hospital In-Patient Enquiry (HIPE), between 1997 and 2011 there were just under 100 discharges with a primary diagnosis of narcolepsy and cataplexy in Ireland. However, most experts would agree that the condition is under diagnosed.

What causes narcolepsy?

The exact cause of narcolepsy is not completely understood. It is generally considered to be triggered by genetic predisposition in combination with environmental factors including infections. Experts believe that in most people, narcolepsy is caused by a reduction in a protein (hypocretin) that is made in the brain. The cause of this reduction is unknown.
Can narcolepsy be treated?

Use of medicines is the most common way to manage narcolepsy. Selecting the correct medicines can be a complex process and some people require more than one medicine. It is not uncommon for patients to try more than one type of medication before finding the best treatment to manage their symptoms. Finding the correct dose may also take some time. In addition certain lifestyle changes are also recommended to help with symptoms. These include:

- Going to bed at the same time every night.
- Taking planned naps during the day if possible. Because of limitations due to work, school etc, it is recommended that these naps are scheduled on a patient by patient basis.
- Avoiding caffeine and alcohol for several hours before bedtime.
- Avoiding smoking especially at night.
- Exercising for at least 20 minutes per day.
- Sleeping in a warm comfortable bedroom.
- Engaging in relaxing activities such as a warm bath before bedtime.

What is Pandemrix®?

Pandemrix® is a vaccine that was used against the H1N1 (2009) influenza (swine flu) virus during the H1N1 influenza pandemic. It protected people from infection and complications due to the H1N1 influenza virus. Over 900,000 doses were used in Ireland.

Is Pandemrix® still in use in Ireland?

No. Pandemrix® has not been recommended in Ireland since January 2011. Doctors were requested to return all stocks of Pandemrix® for disposal.

Is there a difference between the seasonal flu vaccine and Pandemrix®?

Yes. The seasonal flu vaccine and Pandemrix® are two different vaccines. They are manufactured in completely different ways.

Seasonal flu vaccines have been given for more than 60 years to millions of people across the world. Reactions are generally mild and serious side effects are very rare. Narcolepsy has not been reported following seasonal influenza vaccination.

Is there an association between Pandemrix® and narcolepsy?

In August 2010 the European Medicines Agency (EMA) began to investigate a possible link between Pandemrix and narcolepsy, following an increased number of reported cases of narcolepsy among children and adolescents in Finland and Sweden. The IMB was actively involved and contributed to this review.
The EMA review was finalised in July 2011 and it concluded “that in persons under 20 years of age the vaccine may only be used if the recommended seasonal trivalent influenza vaccine is not available and if immunisation against H1N1 is still needed (e.g. in persons at risk of the complications of infection). The Committee confirmed that overall the benefit-risk balance of Pandemrix remains positive”

The EMA noted that the vaccine was likely to have interacted with genetic or environmental factors which might raise the risk of narcolepsy, and that other factors may have contributed to the results. The agency stressed that further research is necessary. Further research is underway internationally. The results of the VAESCO trial (an epidemiology study of narcolepsy and pandemic vaccines which was conducted in nine EU Member states) are expected later this year.

**What is the situation in Ireland?**

It was agreed that the HSE Health Protection Surveillance Centre (HPSC) would work with the IMB and Irish clinical experts in narcolepsy to examine the Irish data and a National Narcolepsy Study Steering Committee was established. The Steering Committee conducted a retrospective population based study and submitted its report to the Department of Health in February 2012.

The study found that an increase in the incidence of narcolepsy was observed from 2009 in children and adolescents in Ireland. There was an increased risk of narcolepsy in children/adolescents vaccinated with Pandemrix® compared with unvaccinated children/adolescents. The absolute number of narcolepsy cases attributable to Pandemrix® vaccination was five per 100,000 vaccinated children/adolescents. The findings are very similar to the results found in the retrospective population-based cohort study conducted in Finland.

**How many affected/cases in Ireland?**

To date, the Irish Medicines Board has received 27 reports with clinical information which confirms a diagnosis of narcolepsy in individuals who were vaccinated with Pandemrix and one report in an individual who received Celvapan.

Twenty four of these reports relate to children/adolescents. The IMB is continuing to follow up with healthcare professionals including specialists involved in the investigation of further patients where a diagnosis of narcolepsy is considered possible regarding the results of their investigations.

**What impacts can narcolepsy have on those affected?**

The impacts on those affected by narcolepsy may vary from person to person and may include medical, educational and social impacts.

**What is being done for those affected?**

There has been active engagement between the Department of Health, the HSE and the Department of Education and Skills to meet the needs of those affected. There has
also been active engagement with representatives from SOUND (Sufferers Of Unique Narcolepsy Disorder).

- The HSE has provided a range of services to those affected including access to rapid diagnosis, clear care pathways, temporary medical cards have been granted for diagnosed cases and expenses incurred by parents are being met by the HSE. Clinicians involved in the treatment of narcolepsy are engaging with international experts in the area.
- Multi-disciplinary assessments which will allow for the appropriate individualised health and educational supports to be put in place have commenced.
- The National Educational Psychological Service (NEPS) is currently engaging with the HSE and with the individual schools and parents of children concerned, to conduct assessment of needs and to identify and provide educational supports for the children and adolescents affected, in conjunction with the National Council for Special Education, based on assessed needs, with those sitting state examinations being prioritised.
- A meeting between SOUND and the State Exam Commission was arranged by the Department of Education and Skills. A central contact point has been established for SOUND with the State Exam Commission, to address issues in relation to the reasonable accommodations which can be made for children with narcolepsy who are taking state exams this year.
- The Department of Health is considering all other possible supports which may need to be put in place for those affected. A Memorandum for Government which will set out the full response to this issue is being prepared for submission in the coming weeks.