## VI.2 Elements for a public summary

### *VI.2.1 Overview of disease epidemiology*

Baclofen is indicated for the relief of spasticity of voluntary muscle resulting from disorders in the central nervous system such as multiple sclerosis or cerebral palsy.

Multiple Sclerosis results in recurrent relapses with a wide range of signs and symptoms.

Slightly more women than men have Multiple Sclerosis, and the disease usually begins in persons aged 20-50 years. It is rare that the disease begins before puberty or after 60 years. Multiple Sclerosis is 10 times more common in people who have parents, siblings or children with Multiple Sclerosis. Approximately 1 in 1,000 Danes have Multiple Sclerosis, i.e. about 5,500 people. Every year 200-250 new patients identified Multiple Sclerosis.

In Denmark there are approximately 10,000 people with a diagnosis of cerebral palsy. It is estimated that between 3000-3500 are under 18 years of age.

The latest figures from the Danish register shows the incidence of cerebral palsy is 2.0 per thousand per year.

This means that about 180 children each year are diagnosed with cerebral palsy in Denmark.

### *VI.2.2 Summary of treatment benefits*

Baclofen works by acting on the central nervous system and may be used for the relief of muscle spasms, cramping or tightness caused by diseases in the central nervous system. When administered intrathecally (directly into the spinal chord), baclofen decreases symptoms of severe spasticity and leads to increased quality of life in chronic spasticity patients. Baclofen helps to increase muscle function and relieve discomfort and pain. In some patients, it may also improve mobility.

### *VI.2.3 Unknowns relating to treatment benefits*

There is no information on use in children under 4 years of age.

### *VI.2.4 Summary of safety concerns*

| **Risk** | **What is known** | **Preventability** |
|---|---|---|
| **Withdrawal symptoms** | When stopping treatment with Baklonova, the dose must be reduced gradually. If treatment is stopped abruptly, you may experience very tense muscles, itching, pins and needles or loss of sensitivity in the skin, low blood pressure, hyperactive state with rapid, uncontrolled spasms, fever, altered psyche and stiff, jerky movements. In rare cases: cramps, muscle degradation with muscle pain and muscle weakness or brownish urine, altered blood clotting, organ failure and possibly death. | Your medication is prescribed by a physician and he/she will advise on how to gradually reduce your dose if you need to stop treatment with baclofen. |
| **Overdose/lack of efficacy** | To achieve the optimal dosage, your doctor will start by giving you a test dose and then very carefully determine the most appropriate dose for you. This will take place over several days. | Your medication is prescribed by a physician and he/she will ensure that the optimal dose is determined by gradually increasing the dose. |
| **Inflammatory accumulation/infiltrate at the tip of the catheter** | Your doctor should be cautious if you have symptoms that can be due to inflammatory accumulation /infiltration at the tip of your catheter. | You are advised to immediately contact your doctor or emergency department if you experience a general feeling of being unwell with fever and stiff neck. |

| Risk | What is known | Preventability |
|---|---|---|
| | | |
| **Use in pregnancy or in breast feeding women** | Baclofen may cause a risk to the unborn child. | Baclofen should not be used during pregnancy unless considered essential and should only be used where the benefits to the mother outweigh possible risks to the child. |
| **Use in children below 4 years of age** | The is very limited information available about use of baclofen in children below 4 year of age. | Baclofen should not be used in children under 4 years of age. |

### *VI.2.5 Summary of additional risk minimisation measures by safety concern*

All medicines have a Summary of Product Characteristics (SmPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimising them. An abbreviated version of this in lay language is provided in the form of the package leaflet (PL). The measures in these documents are known as routine risk minimisation measures.

The Summary of Product Characteristics and the Package leaflet for Baclofen Alternova can be found on the homepage of the national Authorities after the product has been approved.

This medicine has no additional risk minimisation measures.

### *VI.2.6 Planned post authorisation development plan (if applicable)*

Not Applicable.

### *VI.2.7 Summary of changes to the risk management plan over time*

Not Applicable.