## VI.2 Elements for a public summary

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

Dicloxacillin Alternova is used for infections caused by staphylococcus bacteria in among others, the skin and soft tissue, joints and skeleton.

Staphylococcus is a group of bacteria that can cause a number of diseases as a result of infection of various tissues of the body.

About one out of 10 Danes is continuously carriers of yellow staphylococci, which means that they have bacteria on the skin and in the nose. Most of these carriers are healthy and do not have symptoms of staphylococcal disease.

The remainder of the population has yellow staphylococci on the skin and in the nose for shorter periods, and almost all Danes have, at some point in their lives, had abscesses due to staphylococcus bacteria. Yellow staphylococci are the most common cause of infection in wounds after surgery. Fortunately, it is relatively rare that there are serious complications related to an infection with staphylococcus.

Staphylococci are transmitted by direct contact.

Intact skin is an effective defense against getting staphylococcal disease, since bacteria cannot penetrate normal skin. However, there is a risk that the bacteria penetrate the skin if you have eczema, a small wound or surgical site. In the case of admission to hospital, penetration of the skin by needles will increase the risk that bacteria penetrate into the skin. There is a slight risk that the bacteria enter the bloodstream and spread to the internal organs.

Most staphylococcal infections are improves spontaneously without treatment. Deep infections that affect bones or heart valves are severe, and may be lethal if not treated. With proper treatment, fatal cases are rare.

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

Dicloxacillin Alternova is a medicine containing the active substance dicloxacillin, which is an antibiotic belonging to the penicillin group. It inhibits the bacteria from synthesizing a new cell wall and therefore works by killing the bacteria that cause the infection.

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

Not Applicable.

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

| **Risk** | **What is known** | **Preventability** |
|---|---|---|
| Hypersensitivity reactions | Dicloxacillin can cause serious hypersensitivity reactions | The product should not be used in patients with a history of hypersensitivity to dicloxacillin, penicillin or cephalpsporins. |

| Risk | What is known | Preventability |
|---|---|---|
| Overgrowth of non-susceptible organisms | Dicloxacillin can cause overgrowth of bacteria or fungi which is not susceptible to dicloxacillin. | Treatment with dicloxacillin should be discontinued and appropriate treatment of the infection should be initiated. |
| Antibiotic associated colitis and clostridium difficile associated diarrhoea (CDAD) | Dicloxacillin can cause colitis or CDAD which is potentially serious events. | If patients experience diarrhoea during treatment or even several months after treatment with dicloxacillin CDAD should be suspected and investigated and appropriate treatment initiated. |
| Inflammation of the interstitial tissue of the kidney (Interstitial nephritis) | Dicloxacillin can cause inflammation in the kidney. | Doctor and patients are notified about this possible adverse reaction in order to be able to take action if it occurs during treatment with Dicloxacillin Alternova. |
| Use in children below 20 kg | It is recognised that use of Dicloxacillin Alternova, capsules are not appropriate for children under 20 kg. | Not applicable |

### *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 Dicloxacillin Alternova can be found on the web page of the 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.

**Table 1.** Major changes to the Risk Management Plan over time

| **Version** | **Date** | **Safety Concerns** | **Comment** |
|---|---|---|---|
| <number> | <At time of authorisation dd/mm/yyyy> | <Identified Risks<br>Potential Risks<br>Missing information> | |
| <E.g. 7.0> | <E.g. 17/08/2012> | <E.g. Allergic conditions added as an identified risk<br>Hypersensitivity removed as an identified risk<br>Severe infection added as an identified risk<br>Convulsions added as a potential risk> | <E.g. The previous term hypersensitivity was updated to allergic conditions to include angioedema and urticarial> |
| etc. | | | |