

VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Triplo/Triplo Citrus is indicated for treatment of pain such as headache, toothache, menstrual pain, fever of colds disease, joint and muscle pains and migraines.

In medicine pain relates to a sensation that hurts. Pain can be steady and constant or a pulsating pain. Pain may also have a pinching or stabbing sensation.

Pain is the main reason for visiting the emergency department in more than 50% of cases and is present in 30% of family practice visits.

It becomes more common as people get older.

Fever is an abnormally high body temperature, usually accompanied by shivering and headache. About 5% of people who go to an emergency room have a fever.

Although most people consider 37°C normal, it may vary by a degree or more. Other factors, such as menstrual cycle or heavy exercise, can affect body temperature.

VI.2.2 Summary of treatment benefits

Triplo/Triplo Citrus contains acetylsalicylic acid (ASA) and Caffeine and works to ease mild pain such as headache, toothache, menstrual pain, joint and muscle pains and migraines. Caffeine potentiates the pain relieving effect of acetylsalicylic acid.

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

ASA has been marketed for over 100 years and has been in well-established medicinal use for ease of pain. During this time, the clinical efficacy and safety have been thoroughly investigated and well understood as documented in published literature. There is no evidence to suggest that efficacy is reduced or enhanced in any target subpopulation.

VI.2.4 **Summary of safety concerns**

Important identified risks

Risk	What is known	Preventability
Bleeding in the gut (Gastrointestinal Haemorrhage)	Drugs like Triplo/Triplo Citrus, as a class, can cause bleeding in the gut.	Patients who have had bleeding in their gut should not use Triplo/Triplo Citrus.
Bleeding (Haemorrhage)	Drugs like Triplo/Triplo Citrus, as a class, can cause bleeding. There is an increased risk of bleeding particularly during or after surgeries (even in cases of minor procedures, e.g. pulling teeth) or in patients who have certain conditions that affect blood clotting.	Use with caution before surgery, including pulling teeth. It may be necessary to stop treatment for a period of time before surgery. Certain medications should not be taken together with Triplo/Triplo Citrus.
Allergic-type response (Hypersensitivity Reactions)	Drugs like Triplo/Triplo Citrus may cause breathing difficulties, rash or itchy skin reactions.	Patients who have had allergic responses to ASA or other non-steroidal anti-inflammatory medicines (NSAIDS) should not use Triplo/Triplo Citrus.
Stomach or gut sores (Gastric or Duodenal Ulcer)	Drugs like Triplo/Triplo Citrus, as a class, can cause a sore (ulcer) to form in the gut.	If ulcers in the gut occur, the treatment should be stopped. Patients who have a sore in the gut should not use Triplo/Triplo Citrus.
Serious allergic-type skin reactions (Severe Cutaneous Adverse Reactions)	Drugs like Triplo/Triplo Citrus, as a class, may cause serious allergic skin reactions.	Seek medical advice at the first sign of allergic-type skin reactions.
A decrease in kidney function (Deterioration of Renal Function)	Drugs like Triplo/Triplo Citrus, as a class, can cause the kidneys to be less effective in clearing substances from the body and producing urine.	Triplo/Triplo Citrus should be used with caution in patients with decreased kidney function (or not used if this condition is severe).
Medication overuse headache	Long-term and daily use of medication for headache like Triplo/Triplo Citrus can cause headache as a side-effect.	Triplo/Triplo Citrus should not be used for long-term on a daily basis. If medication overuse headache is suspected the doctor should be consulted.
Interaction with other medicines used at the same time (Drug-drug	The use of Triplo/Triplo Citrus with concomitant medicines can alter the effect of Triplo or of the other medicines	The interactions mentioned in the package insert leaflet should be taken into consideration when using

Risk	What is known	Preventability
interactions)		Triplo and other medicines concomitantly.
Worsening of the liver function (Deterioration of hepatic function)	Decrease of liver function can cause accumulation of the active substances and lead to adverse events.	In the case of decreased liver function dose should be adjustment. In the case of severely decreased hepatic function treatment with Triplo is not recommended.
Long term use in the elderly	Long-term use in the elderly should be avoided due to a risk of gastrointestinal bleeding	Long term use in the elderly is not recommended.

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Reye's Syndrome	Triplo/Triplo Citrus is not recommended for use in adolescents/children under 15 years with fever. ASA may be a contributory factor in the causation of Reye's syndrome, a potentially fatal disease that can damage the brain and the liver, in some children.
Overdose	Overdose may be lethal and should be avoided.

Missing information

Risk	What is known
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VI.2.5 Summary of 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 Triplo/Triplo Citrus can be found on the homepage of the Danish and Icelandic Medicines Agency.

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan

None.

VI.2.7 Summary of changes to the Risk Management Plan over time

Not applicable as this is the initial risk management plan.