OPINION ON MEDICINAL PRODUCTS

sumatriptan

SUMATRIPTAN SUN 3 mg/0.5 ml,

solution for injection in a pre-filled syringe

Availability of hybrid

Adopted by the Transparency Committee on 5 October 2022

SUMMARY

The legally binding text is the original French opinion version

Key points

Approval of reimbursement only in the treatment of severe episodic migraine attacks with a major digestive component and rapidly progressive onset, when other oral and nasal migraine-attack treatments cannot be used.

Disapproval of reimbursement in the other marketing authorisation situations.

What progress?

No progress in management.

Role in therapeutic strategy?

Migraine management is based on the treatment of attacks with non-specific molecules (analgesics, non-steroidal anti-inflammatory drugs) or migraine-specific molecules (mainly triptans and ergot derivatives).

In the event of associated digestive disorders during the attack (nausea and/or vomiting), the medicinal products concerned should be administered by a route other than the oral route (intranasal, injectable or rectal).

The recent 2021 recommendations of the French Society for Migraine and Headache Studies (SFEMC) also advocate the use of metoclopramide (intravenous or suppository) as a specific treatment for attacks associated with severe nausea and/or vomiting.

A basic treatment can be introduced, according to the symptomatology of the attacks (frequency and severity) and their impact on daily life.

Role of the medicinal product

Considering:

- **the evidence of the superiority of sumatriptan 3 mg by injection only over placebo in the treatment of moderate to severe episodic migraine attacks,**
- **the lack of efficacy and safety data versus a clinically relevant comparator,**
- **and taking into account the known safety profile of injectable sumatriptan,**

SUMATRIPTAN SUN 3 mg/0.5 ml, solution for injection in a pre-filled syringe (sumatriptan) is a therapeutic option for the treatment of severe episodic migraine attacks with a major digestive component and rapid progressive onset, when other oral and nasal treatments for migraine attacks cannot be used.

In the other situations covered by the marketing authorisation, SUMATRIPTAN SUN 3 mg/0.5 ml, solution for injection in a pre-filled syringe (sumatriptan) has no role in the therapeutic strategy.

Committee's conclusions

Clinical Benefit

- Migraine is a chronic disabling condition which, due to the frequency and severity of attacks, can lead to severe impairment of quality of life.
- SUMATRIPTAN SUN 3 mg/0.5 ml, solution for injection in pre-filled syringe (sumatriptan) is used for symptomatic treatment.
- Considering:
  - the evidence of the superiority of sumatriptan 3 mg by injection only over placebo in the treatment of moderate to severe episodic migraine attacks,
  - and taking into account the known safety profile of injectable sumatriptan,

  the efficacy/adverse effect ratio of SUMATRIPTAN SUN 3 mg/0.5 ml, solution for injection in pre-filled syringe (sumatriptan) is significant in the treatment of severe episodic migraine attacks with a major digestive component and rapid progressive onset, when other oral and nasal treatments for migraine attacks cannot be used.

  In the other situations covered by the marketing authorisation, the efficacy/adverse reaction ratio of SUMATRIPTAN SUN 3 mg/0.5 ml, solution for injection in pre-filled syringes (sumatriptan), cannot be established.
- Medicinal alternatives are available.
- SUMATRIPTAN SUN 3 mg/0.5 ml, solution for injection in a pre-filled syringe (sumatriptan) is a therapeutic option for the treatment of severe episodic migraine attacks with a major digestive component and rapid progressive onset, when other oral and nasal treatments for migraine attacks cannot be used.

  In the other situations covered by the marketing authorisation, SUMATRIPTAN SUN 3 mg/0.5 ml, solution for injection in a pre-filled syringe (sumatriptan) has no role in the therapeutic strategy.

Public health benefit

Considering:

- the severity of the disease and its prevalence
- the partially met medical need,
- the lack of an additional response to the identified need due to:
  - the lack of any additional impact on morbidity in the treatment of migraine attacks,
  - the lack of evidence of any additional impact on quality of life
  - the lack of evidence of any additional impact on the delivery of care

SUMATRIPTAN SUN 3 mg/0.5 ml, solution for injection in a pre-filled syringe (sumatriptan) is not likely to have an additional public health benefit.

Taking into account all these elements, the Committee considers that the actual clinical benefit of SUMATRIPTAN SUN 3 mg/0.5 ml, solution for injection in a pre-filled syringe (sumatriptan) is:

- **substantial only in the treatment of severe episodic migraine attacks with a major digestive component and rapid progressive onset, when other oral and nasal treatments for migraine attacks cannot be used.**

- **insufficient to justify public funding in the other marketing authorisation situations**.

The Committee:

- **approves inclusion in the list of proprietary medicinal products qualifying for reimbursement under social security and in the list of proprietary medicinal products approved for community use only in the treatment of severe episodic migraine attacks with a major digestive component and rapidly progressive onset, when other oral and nasal treatments for migraine attacks cannot be used.**
- **disapproves inclusion in the list of proprietary medicinal products qualifying for reimbursement under social security and in the list of proprietary medicinal products approved for use in other marketing authorisation situations.**

Proposed reimbursement rate: 65%

Clinical Added Value

Considering:

- the evidence of the superiority of sumatriptan 3 mg by injection only over placebo in the treatment of moderate to severe episodic migraine attacks,
- the lack of efficacy and safety data versus a clinically relevant comparator,
- and taking into account the known safety profile of injectable sumatriptan,

The proprietary medicinal product SUMATRIPTAN SUN 3 mg/0.5 ml, solution for injection in a prefilled syringe (sumatriptan) provides no clinical added value (CAV V) in the treatment of severe episodic migraine attacks with a major digestive component and rapid progressive onset, when other oral and nasal treatments for migraine attacks cannot be used.