

SUMMARY

methacholine chloride

**PANPHARMA
METHACHOLINE
CHLORIDE 100 mg,****powder for solution for nebulisation for inhalation by nebulisation**

Initial inclusion

**Original French opinion adopted by the Transparency Committee on 8
November 2023****The legally binding text is the original French opinion version****Transparency Committee's Conclusions****Clinical Benefit**

- ➔ Bronchial hyperreactivity is a tendency of smooth muscle in the bronchial tree to contract more intensely in response to a given stimulus compared to the response obtained in healthy people. It is observed in most patients with asthma. Asthma can have a major impact on quality of life and is associated with a risk of severe, potentially life-threatening exacerbations.
Bronchial hyperreactivity may also be associated non-respiratory conditions (heart failure, inflammatory bowel disease, gastro-oesophageal reflux, systemic disease). The symptoms of bronchial hyperreactivity are commonplace, consisting of dyspnoea, which may be associated with wheezing, and irritable cough.
- ➔ This is a diagnostic medicinal product.
- ➔ The efficacy/adverse effects ratio is low.
- ➔ This is a first-line treatment in view of the therapies available (see 5.1) for the diagnosis of non-specific bronchial hyperreactivity in adults and children (under 5 years of age), who are capable of performing reproducible spirometry, whose spirometry is normal and who do not present with clinically apparent asthma, but who have medical history suggesting this condition.

→ Public health benefit

In view of:

- the seriousness of the diagnosed condition and its prevalence;
- the partially met medical need;
- the *partial response* to the identified need with:
 - an expected additional impact on the diagnosis of non-specific hyperreactivity in adults and children (at least 5 years old), which do not present with clinical apparent asthma, but who have medical history suggesting this condition;
 - the lack of additional impact on delivery of care;
 - the lack of expected impact on the care and/or life pathway;

PANPHARMA METHACHOLINE CHLORIDE (methacholine chloride) is unlikely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the clinical benefit of PANPHARMA METHACHOLINE CHLORIDE 100 mg, powder for solution for inhalation by nebulisation (methacholine chloride), is moderate in the MA indication.

The Committee approves inclusion of PANPHARMA METHACHOLINE CHLORIDE 100 mg, powder for solution for inhalation by nebulisation (methacholine chloride), in the list of covered drugs for inpatients in the indication and at the MA dosages.

Clinical Added Value

In view of:

- the use of methocholine for several decades for the diagnosis of non-specific bronchial hyper-reactivity in adults and children (at least 5 years old), who are capable of performing reproducible spirometry, whose spirometry is normal and who do not present with clinically apparent asthma, but who have medical history suggesting this condition;
- the evidence of the efficacy of methacholine based on bibliographic data;
- the poor robustness of the findings of the clinical studies linked with the methodological limitations of the studies provided;
- the good safety profile of methacholine;
- the partially met medical need;

the Committee deems that PANPHARMA METHACHOLINE CHLORIDE 100 mg, powder for solution for inhalation by nebulisation (methacholine chloride), provides no clinical added value (CAV V) in the current diagnostic strategy in respect of bronchial hyperreactivity.