

**17.07.2019 TARİHLİ VE E.111657 SAYILI OKSİMETAZOLİN VE KSILOMETAZOLİN İÇEREN
PREPARATLAR_ENG**

MINISTRY OF HEALTH OF THE REPUBLIC OF TURKEY Medicines and Medical Devices Agency
of Turkey

Number : 62820468-000-E.111657 Subject : Preparations Containing Oxymetazoline and
Xylometazoline NORMAL

17.07.2019

DOSSIER

The preparations containing Oxymetazoline and Xylometazoline have been evaluated by the
“Clinical Evaluation Commission on Medicinal Products for Human Use”.

In accordance with the decision adopted; - The association decision dated 10.04.2018, with
No. 24533, on “Cold and Cough Medicines”, the decision dated 07.07.2008, with No. 43710, on
“Preparations Containing Phenylephrine, Ephedrine, Pseudoephedrine, Oxymetazoline and
Xylometazoline”, the decision dated 16.03.2010, with No. 20514 on “Preparations Containing
Oxymetazoline and Xylometazoline” and the decision dated 23.07.2013, with No. 80969, on
“Medicines Used in Cold and Cough Treatment” have been annulled.

- Generally, the amount of active substance in nasal topical decongestant products should
not surpass 0.025% for oxymetazoline and 0.05% for xylometazoline in pediatric use.

- It is necessary to review and standardize the indication, posology and
warnings/precautions sections on the pediatric use of oxymetazoline (0.025%) in accordance with
statements suitable for the following pediatric age groups. a) It is contraindicated for children
below the age of 2 years. b) It should not be used in children aged between 2-6 years (age interval
of 2 years and above to 6 years). c) The statement reading “It may be used provided that a
benefit/risk assessment is made by the physician” should be included to the warnings/precautions
section of the product’s SPC/PL for children aged between 6-12 years (age interval of 6 years and
above to 12 years).

- It is necessary to review and standardize the indication, posology and
warnings/precautions sections on the use of 0.05% form of oxymetazoline in accordance with
statements suitable for the following age groups. - a) It is contraindicated for children below the
age of 6 years. - b) It should not be used in children aged between 6-12 years (age interval of 6
years and above to 12 years). c) The statement reading “It may be used in adequate age groups in
children provided that a benefit/risk assessment is made by the physician” in the
warnings/precautions section of the product’s SPC/PL in children aged between 6-12 years (age
interval of 6 years and above to 12 years).

- It is necessary to review and standardize the indication, posology and
warnings/precautions sections on the pediatric use of xylometazoline (0.05%) in accordance with
statements suitable for the following pediatric age groups. a) It is contraindicated for children
below the age of 2 years.

- b) It should not be used in children aged between 2-6 years (age interval of 2 years and
above to 6 years). c) The statement reading “It may be used provided that a benefit/risk
assessment is made by the physician” in the warnings/precautions section of the product’s SPC/PL
in children aged between 6-12 years (age interval of 6 years and above to 12 years).

- It is necessary to review and standardize the indication, posology and
warnings/precautions sections on the use of 0.1% form of xylometazoline in accordance with
statements suitable for the following age groups. - a) It is contraindicated for children below the
age of 6 years. - b) It should not be used in children aged between 6-12 years (age interval of 6
years and above to 12 years). c) The statement reading “It may be used in adequate age groups in
children provided that a benefit/risk assessment is made by the physician” should be added to the
warnings/precautions section of the product’s SPC/PL.

- All nasal topical decongestant products containing the active substances Oxymetazoline and Xylometazoline, including the products with an active substance amount lower than those specified above are contraindicated for children below the age of 2 years.

I hereby would like to inform you and kindly request that any views, proposals and remarks regarding the decision adopted should be submitted to the Clinical Evaluation Unit until 16.08.2019 and that no application is made to the Pharmacological Evaluation Unit regarding products containing topical corticosteroid within the referred period.

Spec. Pharm. Hacer COŞKUN ÇETİNTAŞ on behalf of the President of the Agency Head of Department

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Effective as of 2023

MINISTRY OF HEALTH OF THE REPUBLIC OF TURKEY Medicines and Medical Devices Agency of Turkey

Number : 77893119-000-E.188534 Subject : Products with the active substance Aripiprazole
NORMAL 30.10.2018

DOSSIER

The literature annexed to the objections received from companies regarding the association announcement entitled "Products with the active substance Aripiprazole", dated 28.02.2018, with No. E.39828, has been evaluated by the "Clinical Evaluation Commission on Medicinal Products for Human Use" and it has been decided to annul the referred association decision.

It is necessary to amend the indications section of the medicinal products for human use containing the active substance "Aripiprazole" as follows: "It is indicated as an add-on therapy for enhancing antidepressant therapy in major depression patients who are resistant to antidepressant therapy."

I hereby submit for your information and kindly request that the SPC/PL applications for the products in which abovementioned changes are made are submitted to the Pharmacological Evaluation Unit until 12.11.2018 for review.

Dr. Hakkı GÜRSÖZ President of the Agency

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