



Rasilez HCT (aliskiren/hydrochlorothiazide) medicine and missing safety informations in the Summary of the Product Characteristics (SmPC) and in the Package Leaflet (PL)

The Marketing Authorization (MA) of the medicinal product Rasilez HCT (aliskiren/hydrochlorothiazide) is currently revoked, on the initiative of the Marketing Authorization Holder and not for safety reasons, in all European Union Countries (EC Decision C(2021) 9911), including Italy, but several product packages are still present on the Italian national market while stocks last.

The safety information relating to the active substance hydrochlorothiazide has recently been updated with the inclusion of the risk of acute respiratory distress syndrome (ARDS) but this update is not present in the SmPC and in the PL of Rasilez HCT packages still on the market.

The attention of healthcare professionals and citizens is therefore drawn to the following safety information, relating to the active substance hydrochlorothiazide, missing in the SmPC and in the PL:

Summary of Product Characteristics

Section 4.4

Hydrochlorothiazide

Acute Respiratory Toxicity

Very rare severe cases of acute respiratory toxicity, including acute respiratory distress syndrome (ARDS) have been reported after taking hydrochlorothiazide. Pulmonary oedema typically develops within minutes to hours after hydrochlorothiazide intake. At the onset, symptoms include dyspnoea, fever, pulmonary deterioration and hypotension. If diagnosis of ARDS is suspected, X should be withdrawn and appropriate treatment given. Hydrochlorothiazide should not be administered to patients who previously experienced ARDS following hydrochlorothiazide intake.

Section 4.8

Acute respiratory distress syndrome (ARDS) (see section 4.4)

Package Leaflet

Section 2

2. What you need to know before you <take> <use> X

Warnings and precautions

Talk to your doctor <or> <pharmacist> <or nurse> before <taking> <using> X

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If you experienced breathing or lung problems (including inflammation or fluid in the lungs) following hydrochlorothiazide intake in the past. If you develop any severe shortness of breath or difficulty breathing after taking X, seek medical attention immediately.

4. Possible side effects

Very rare:

Acute respiratory distress (signs include severe shortness of breath, fever, weakness, and confusion).

More information on the medicinal product:

Rasilez HCT (aliskiren/hydrochlorothiazide) medicine in the following packages:

- Rasilez HCT 150 mg/12,5 mg film-coated tablets
- Rasilez HCT 150 mg/25 mg film-coated tablets
- Rasilez HCT 300 mg/12,5 mg film-coated tablets
- Rasilez HCT 300 mg/25 mg film-coated tablets

was indicated in:

- the treatment of essential hypertension in adults
- in patients whose blood pressure is not adequately controlled with aliskiren or hydrochlorothiazide in monotherapy
- as replacement therapy in patients adequately controlled with aliskiren and hydrochlorothiazide, administered concomitantly, at the same dosage as the combination.

With EC Decision C(2021) 9911 the Marketing Authorization (MA) is revoked at the request of the Marketing Authorization Holder for commercial reasons.