# **Baloxavir marboxil**

## **Initial supply and re-ordering**

Baloxavir marboxil will be sourced by local pharmacy procurement team free of charge from Roche Products Ltd. Baloxavir is available as 40mg tablets in packs of 2 tablets.

*Initial Order:*

Please order 6 packs of baloxavir capsules (2x 40mg) by emailing the electronic drug delivery request form to ukremap-cap@icnarc.org.

*Reordering:*

When stock falls to 4 packs of baloxavir capsules (2 x 40mg), please make the required re-order by submitting a new electronic drug delivery request form to ukremap-cap@icnarc.org Please only order enough stock to ensure you do not have more than the initial order.

Orders placed before 12:00 will aim to be delivered to site the following working day, however, some sites in the highlands and islands will be in line with the delivery schedule followed for all other orders placed with Roche. If you have any questions/concerns about the drug delivery, please contact welwyn.cpg\_general@roche.com.

**All sites** will need to ensure clear storage separation between stock for this study and general hospital stock for flu patients (or stock used for other clinical trials), as well as having some way of identifying the difference between stock when dispensing and checking. This could be done via a few ways such as adding an additional label on receipt of stock stating ‘to be used in the REMAP CAP trial only’ and storing in different areas of pharmacy.

## **Storage**

As per SmPC

No temperature excursion reporting required. Follow Trust SOPs to manage temperature excursions.

## **Dispensing quantities**

Adults and adolescents (≥ 12 years of age)

<40kg 2 mg/kg on days 1 and 4 to max of 40 mg

40kg to 80kg Baloxavir 40mg once daily by mouth on day 1 and day 4 ie 1 x 2 x 40mg pack
>80kg Baloxavir 80mg once daily by mouth on day 1 and day 4 ie 2 x 2 x 40mg packs

## **Returns and Destructions**

During the study for any patient returns or destruction requests please contact

ukremap-cap@icnarc.org

## **FAQs**

**Q. Can baloxavir tablets be cut or crushed for patients who have swallowing difficulties or who have a feeding tube?**

A. The tablet must **not** be crushed or split. It can be dissolved if needed: Place tablet in 100ml medicine bottle, add 50 ml of water for irrigation at ambient temperature and shake for 10 minutes.
Add 50ml ORA-Blend to mask the taste, shake again to mix well. The mixture has not been tested for enteral administration. ORA-Blend is the only option: do NOT mix with food or juice.

If administering via a feeding tube (where taste is not an issue), the tablets can be dissolved in 100ml water. (While the company’s in house data on dispersing tablet has not been tested for enteral administration, baloxavir suspension is licensed in the US for administration via enteral feeding tube, suggesting drug interaction with tubing is unlikely to be an issue. Given the licensed baloxavir 2mg/mL suspension is bioequivalent to baloxavir tablet, and the suspension is a simple suspension formulation (excipients: non-colloidal silicon dioxide, hypromellose, maltitol, mannitol, povidone K25, sodium chloride, strawberry flavour, sucralose and talc), the administration of dispersed tablet suspension is likely to have minimal impact on bioavailability.)

**Q. How should the tablets be taken?**A. The tablets must be swallowed whole with or without food.
Baloxavir should not be taken with products that contain polyvalent cations such as laxatives, antacids or oral supplements containing iron, zinc, selenium, calcium or magnesium

**Q. Do tablets contain lactose?**
The tablets contain lactose as an excipient, so patients who are lactose intolerant should not be randomised to receive this medicine.