

FOI 23/204 - Clinical overview, Carbocisteine 750 mg/10 ml Sugar Free Oral Solution in Sachet

REQUEST

20 March 2023

I should be grateful if you could provide me with copies of the Clinical overview for the following product:

- Carbocisteine 750 mg/10 ml Sugar Free Oral Solution in Sachet
- PL 17509/0074
- MAH: Esteve Pharmaceuticals (formerly Intrapharm Laboratories Limited)
- Authorised March 2015

MHRA REPLY

26 March 2023

Thank you for your email.

Carbocisteine unither pharmaceuticals 750mg/10ml sugar-free oral solution in sachet, Carbocisteine 750mg/10ml sugar-free oral solution in sachet (PL 17509/0074) was granted by a CoA on 26 March 2015.

The original product licence (PL 41322/0001) was granted by an incoming mutual recognition procedure (MRP) on 25 June 2013, with France as the Reference Member State (RMS - FR/H/0536/001). As this product licence was approved through another member state by MRP, We are exempting the clinical overview under Section 27 of the FOIA (international relations) and advise that you contact the French regulator for consideration under their FOI Act.

Name

The French National Agency for Medicines and Health Products Safety

Address

143-147 bd Anatole France
FR-93285 Saint Denis Cedex

Country

France

Phone

+33 1 55 87 30 00

Email

communication.ANSM@ansm.sante.fr

Website

www.ansm.sante.fr

If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask for an internal review. Please reply to this

email, within two months of this reply, specifying that you would like an Internal Review to be carried out.

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely

MHRA Customer Experience Centre
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU