

IMPORTANT MEDICINE SAFETY INFORMATION

CORENZA-C® EFFERVESCENT TABLETS (C661 (Act 101/1965)):

AMENDMENT TO PRODUCT LABELLING – NOT TO BE USED

IN CHILDREN UNDER 12 YEARS OF AGE

30 September 2025

Dear Healthcare Professional,

Adcock Ingram Limited in collaboration with the South African Health Products Regulatory Authority (SAHPRA), would like to inform you of the amended product labelling for Corenza-C® Effervescent Tablets to align with the recommended contraindicated use of aspirin in children under the age of 12 years because of the risk of Reye's Syndrome.

Background

Corenza-C® contains aspirin, and it is used for the relief of symptoms associated with rhinitis, laryngitis and symptoms of colds and influenza.

Reye's Syndrome is a rare but serious condition that primarily affects children and teenagers recovering from viral illness (most commonly varicella zoster and influenza virus).^{[1] [2, p. 2]} While multiple factors are postulated to predispose to, and cause the development of Reye's syndrome, the association between Reye's Syndrome and aspirin is well documented in the literature. ^[1, p. 1] The evidence for an association between aspirin and influenza/varicella infection leading to Reye's Syndrome is based on epidemiological research and surveillance reports. ^{[1, p. 1] [3, p. 2]}

As result, the dosage has been amended as follows:

Previous Dosage Recommendation	Current Dosage recommendation
<u>Dosage</u> Adults: - 2 tablets immediately, thereafter 1 tablet 3 to 4 times a day as required. Children - over 6 years: - Half a tablet 3 to 4 times a day.	<u>Dosage</u> Adults and children older than 12 years: - 2 tablets immediately, thereafter 1 tablet 3 to 4 times a day as required. Paediatric population: - Corenza-C should not be used in children under the age of 12 years

This change will be implemented into Corenza-C® Effervescent Tablets printed packaging material (Professional Information (PI), Patient Information Leaflet (PIL), Carton and Label) in due course.

Advice for healthcare professionals:

- HCPs and consumers are advised to reference the PI and PIL hosted on the SAHPRA website (<https://pi-pil-repository.sahpra.org.za/>) and the OTC Directory ([OTC Directory - SAHPRA](#)). This ensures that healthcare professionals and patients have immediate access to the updated PI and PIL, thereby supporting safe and informed use of Corenza-C®. The updated PI and PIL are also available on www.adcock.com and can be accessed using the QR Code below:



Advice for Healthcare Professionals to provide to patients:

HCPs should inform patients that:

- aspirin-containing medicines such as Corenza-C® are for short-term use only and should not be used for prolonged or extended use.
- Corenza-C® Effervescent Tablets are not suitable for use in children under the age of 12 years.
- Patients should be encouraged to follow the instructions for use in the PIL which can be located on the SAHPRA PI-PIL repository.

Patients should be reminded to always consult a Healthcare Professional before giving Corenza-C® to someone else or before sharing medicines recommended specifically for them with another person.

Patients should be alerted about the risks, signs and symptoms of Reye's syndrome associated with the use of aspirin-containing medicines in chickenpox and influenza.

Patients should be made aware that non-serious side effects, which are typically mild, may be experienced, while using any medicine.

Healthcare professionals should emphasise the importance of using the PIL for guidance and seeking advice from a doctor or pharmacist if they experience any side effects associated with the use of Corenza-C® effervescent tablets.

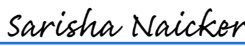
Healthcare professionals are encouraged to report any adverse drug reactions (ADRs) or product quality problems associated with the use of Corenza-C® effervescent tablets to Adcock Ingram by completing an ADR reporting form accessible via this link <https://www.adcock.com/contact-us> or to contact us on:

Adcock Ingram Pharmacovigilance department
Tel: 073 540 7052 / 011 635 0134
Email: adcock.aereports@adcock.com

Alternatively, healthcare professionals may use the following eReporting link <https://primaryreporting.who-umc.org/ZA> available on the SAHPRA website (www.sahpra.org.za).

Additionally, reporting can be done via the Med Safety App. The App can be downloaded into a smart mobile phone through Google Play or App Store. For more information on Med Safety App, please use the following link: <https://medsafety.sahpra.org.za/>.

Yours faithfully,

Deon Poovan Head: Group Regulatory Compliance and Responsible Pharmacist <i>Adcock Ingram Limited</i>  Deon Poovan (Oct 2, 2025 12:13:08 GMT+2) Signature	Sarisha Naicker Head: Group Medicines Safety QPPV <i>Adcock Ingram Limited</i>  Sarisha Naicker (Oct 2, 2025 12:16:56 GMT+2) Signature
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References:

- [1] J. Chapman and J. Arnold, "Reye Syndrome," 4 4 2023. [Online]. Available: <https://www.ncbi.nlm.nih.gov>.
- [2] A. Elwadhi, "Reye's Syndrome, still an enigma after 50 years: Have the curtains finally been drawn?," *Indian Pediatr Case*, no. 1, pp. 146-8, 2021.
- [3] S. Burle and V. Desai, "Managing Risk of Reye's Syndrome in children on long-term Aspirin treatment," *European Journal of Medical Case Reports*, vol. 2, no. 1, pp. 106-107, 2017.