



National Agency for Food & Drug Administration & Control (NAFDAC)

NAFDAC Public Assessment Report (NAPAR)

Sevoflurane AIT 100%v/v inhalation

Sevoflurane 100%v/v

A4-102125

Smart Way Pharma Limited

This report reflects the scientific assessment for the approval of Sevoflurane AIT. The product was licenced in May 2026.
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PART 1: ABSTRACT

Sevoflurane AIT containing sevoflurane manufactured at Accima International Trading (AIT), Plot No.41 - 6th Industrial Zone Extension, Giza, Egypt was granted marketing authorization by NAFDAC for the induction and maintenance of general anesthesia on 31 May 2026.

Sevoflurane is indicated for induction and maintenance of general anesthesia.

For details on the uses of this product and for side effects and warnings, see the summary of product characteristics (SmPC), which can be found in the NAFDAC Greenbook.

The marketing authorization of Sevoflurane by NAFDAC is based on the review of the Common Technical Document (CTD) dossier submitted to ascertain the quality, safety, and efficacy.

All accepted presentations of Sevoflurane have been shown in part 2 of this report. The summary of product characteristics (SmPC) and the approved labelling have been presented in part 3 and part 4 respectively.

Scientific discussion on the quality, non-clinical and clinical aspects of Sevoflurane has been presented in part 5 of this report.

The detailed steps taken to approve Sevoflurane by NAFDAC have been presented in part 6 of this report.

No action or steps have been taken following the marketing authorization of Sevoflurane.

PART 2: ACCEPTED PRESENTATIONS

Product name	Active ingredients	Pharmaceutical form/description	Packaging	Pack size
Sevoflurane AIT	Sevoflurane 100%	Colourless, clear non-flammable and volatile inhalation liquid	250 mL amber type III coloured glass bottle with filling adaptor. Available in a carton.	1 x 250 mL

PART 3: SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Refer to the NAFDAC Greenbook URL below for the SmPC

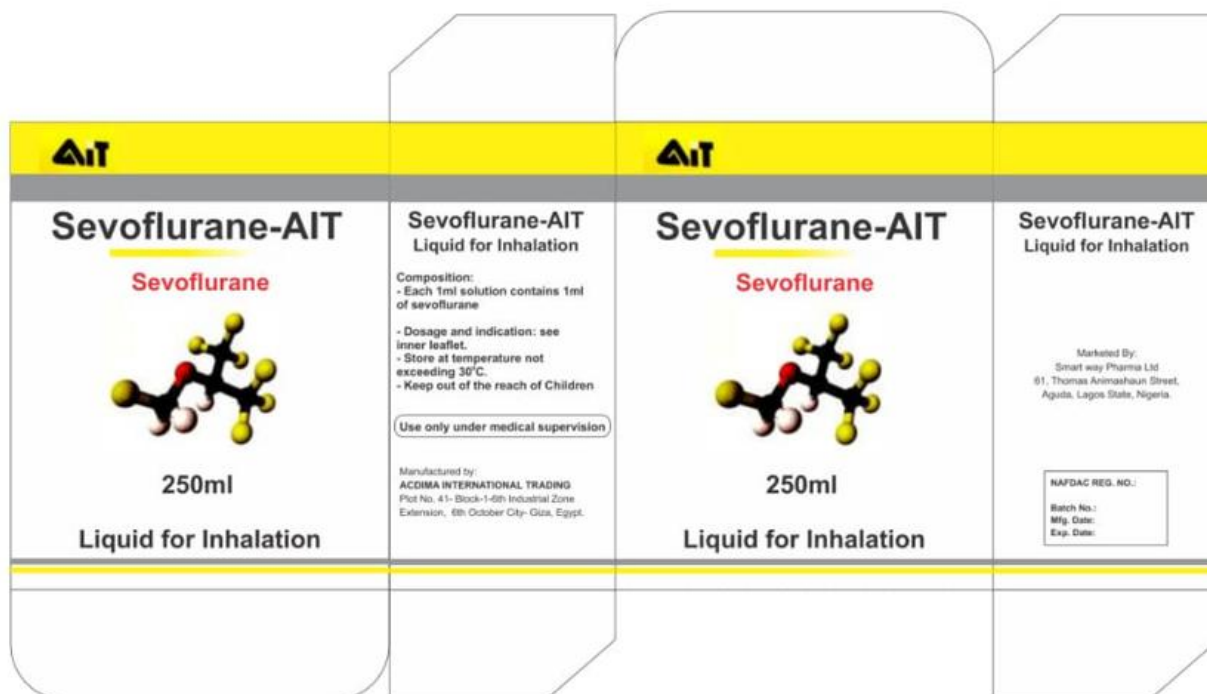
See: <https://greenbook.nafdac.gov.ng/>

PART 4: LABELLING

Primary label



Secondary label



PART 5: SCIENTIFIC DISCUSSION

5.1. About the Product

5.1.1 Name of the product

Sevoflurane AIT inhalation 100%v/v

5.1.2 Therapeutic indication

Sevoflurane AIT is indicated for induction and maintenance of general anesthesia.

5.1.3 Applicant

Smart Way Pharma Limited, No 61, Thomas Animashanu Street, Aguda, Lagos.

5.1.4 Pharmaceutical form

A colourless, clear non-flammable and volatile inhalation liquid in amber glass bottle.

5.1.5 Storage

Do not store above 30°C.

5.1.6 Shelf life

36 months

5.1.7 Product presentation

A colourless, clear non-flammable and volatile inhalation liquid filled in a 250 mL amber type III coloured glass bottle with filling adaptor in a carton box with insert.

5.2 Drug Substance

5.2.1 Manufacturer

Sevoflurane is manufactured by Shandong New Time Pharmaceutical Co. Limited. No.1, North Outer Ring Road, Feixian County, Shandong Province, China.

The API specifications are pharmacopoeial based.

Stability testing was conducted according to the requirements of NAFDAC. The proposed re-test period is justified based on the stability results when the API is stored in line with the storage statement.

5.3 Other ingredients

There are no other ingredients used in the formulation of sevoflurane AIT.

5.4 Drug Product

5.4.1 Drug product manufacturer

Acdima International Trading, plot no. 41-6th Industrial Zone Extension, Gazi, Egypt.

5.4.2 Pharmaceutical development

The objective of the pharmaceutical development is to manufacture a generic which is stable, deliver the intended performance, safe and bioequivalent in term of efficacy to the reference product, Ultane, manufactured by Maruishi Pharmaceutical Co. Japan.

The product is manufactured by an aseptic filling process followed by capping, labelling and packaging of the product. All the manufacturing processes were validated.

5.4.3 Specification

The finished product specification is based on ICH Q6A guidelines and USP general chapters.

The finished product specifications include appearance, water content, average volume, total impurities by gas chromatography, identification by gas chromatography, non-volatile residue test, assay by gas chromatography, related substances, and microbiological test. The test procedures have been adequately validated.

5.4.4 Stability

Stability studies have been conducted at 30°C/75%RH at long-term storage conditions and for six months at accelerated conditions in the packaging intended for marketing the product. The product proved to be quite stable in these conditions, with no apparent negative trend. Based on the data submitted, the proposed shelf life of 36 months and 'Do not store above 30°C' have been accepted.

5.5 Conclusion

Based on the assessment of data submitted on quality, safety and efficacy, the benefit–risk profile of sevoflurane AIT was acceptable for the following indication: 'for the induction and maintenance of general anesthesia', and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Smart Way Pharma Limited, No 61, Thomas Animashanu Street, Aguda, Lagos. submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of Sevoflurane AIT.

The following are the steps for registration

September 2025	Date of receipt of application
February 2026	Date of conclusion of assessment
December 2025	Date of inspection
31 May 2026	Date of issuance of Marketing Authorization

PART 7: STEPS TAKEN FOLLOWING REGISTRATION

No action or steps have been taken following marketing authorization of Sevoflurane AIT