For high-risk neuroblastoma patients with at least a partial response to multiagent, multimodality therapy including immunotherapy, IWILFIN may help reduce the risk of relapse[1]

"I will do all I can to protect my patients from relapse."

Actor portrayals.

The first and only oral maintenance therapy shown to cut the risk of high-risk neuroblastoma relapse in half[1]

iwilfin™
(eflornithine) tablets
partners in protection

INDICATION

IWILFIN is indicated to reduce the risk of relapse in adult and pediatric patients with high-risk neuroblastoma (HRNB) who have demonstrated at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions
IWILFIN can cause myelosuppression. CBC and liver function tests should be performed before starting treatment and as clinically indicated for the duration of treatment. Withhold, reduce the dose, or permanently discontinue IWILFIN based on severity.

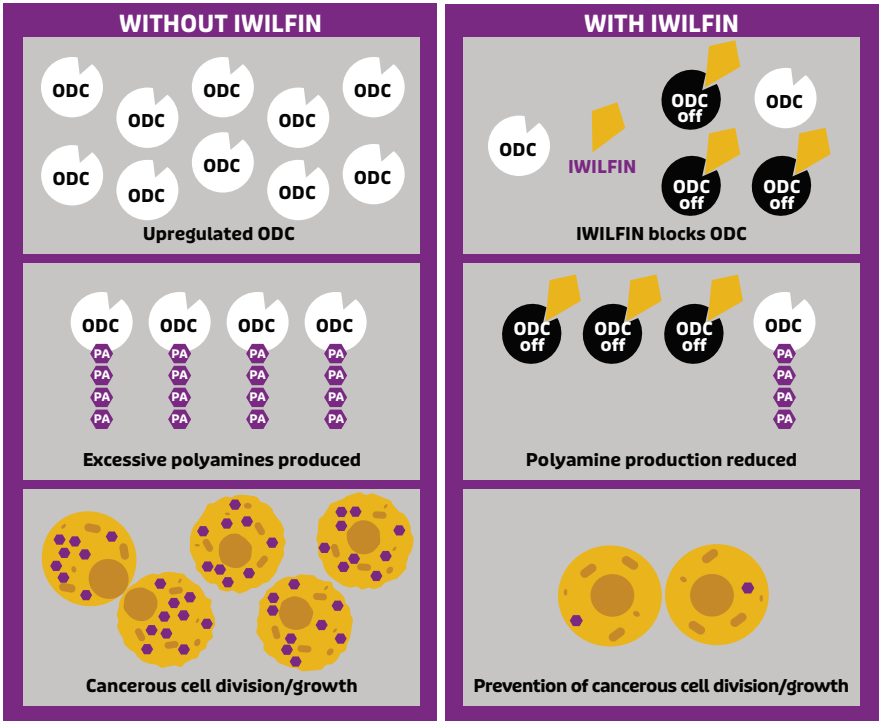
Please see additional Important Safety Information throughout and accompanying full Prescribing Information.

Mechanism of Action

IWILFIN targets specific oncogenic pathways in neuroblastoma

IWILFIN works by blocking an enzyme called ornithine decarboxylase (ODC). ODC is the first and rate-limiting enzyme in the biosynthesis of polyamines, which are important to tumor proliferation.[1]

How IWILFIN works in high-risk neuroblastoma



IMPORTANT SAFETY INFORMATION (CONT'D)

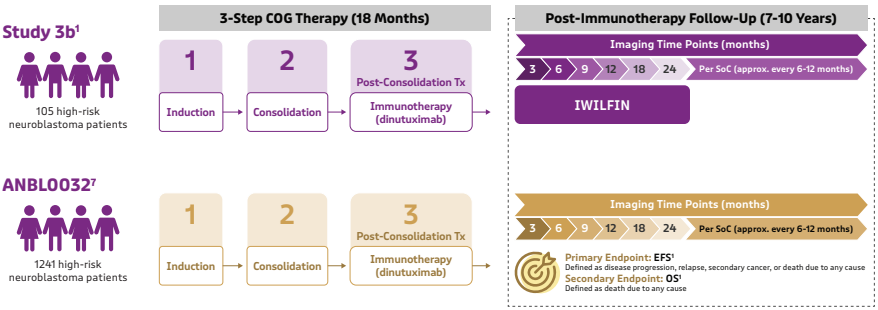
IWILFIN can cause hearing loss. Monitor hearing before and during treatment with IWILFIN. Withhold, reduce the dose, or permanently discontinue IWILFIN based on severity.

Study Design

The addition of IWILFIN maintenance therapy following standard of care upfront treatment[1]

The efficacy of IWILFIN is based on an externally controlled study comparison of outcomes between Study 3b (investigational arm) and Study ANBL0032 (clinical trial–derived external control arm).

- Study 3b (IWILFIN-treated patients): A multicenter, open-label, non-randomized trial. Pediatric patients with high-risk neuroblastoma who demonstrated at least a partial response to the standard of care upfront therapy, consistent with ANBL0032 treatment protocol, received IWILFIN orally twice daily for a maximum of 2 years
- Study ANBL0032 (external control): A multicenter, open-label, randomized trial of dinutuximab, granulocyte-macrophage colony-stimulating factor, interleukin-2, and cis-retinoic acid compared to cis-retinoic acid alone in pediatric patients with high-risk neuroblastoma



COG, Children's Oncology Group; EFS, event free survival; OS, overall survival; PA, polyamine; SoC, standard of care; Tx, treatment.

Patients had to meet specific eligibility criteria in order to be considered for the comparative analysis between Study 3b and ANBL0032.

The overall goal of the eligibility criteria was to find groups of patients that achieved the same remission status at the end of COG standard of care upfront therapy so that the only difference was whether the patient received IWILFIN or not.

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Efficacy

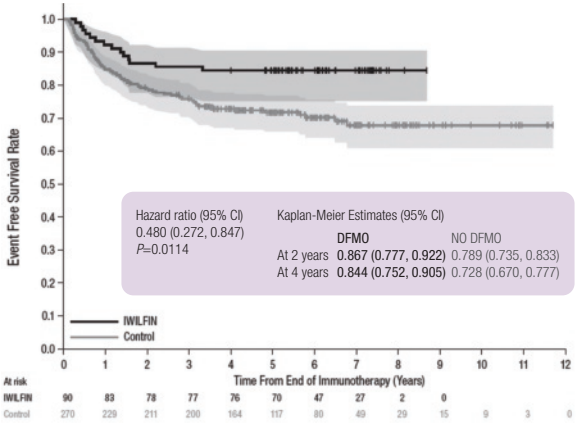
IWILFIN improved outcomes in primary matched comparison[1,2]

52% reduction in the risk of relapse with IWILFIN

Primary Endpoint: EFS

EFS is defined as the period from the last day of immunotherapy until the first occurrence of relapse, progressive disease, secondary cancer, or death.

In supplementary analyses, the reduced risk of relapse for patients taking IWILFIN ranged from 57% to 41%.

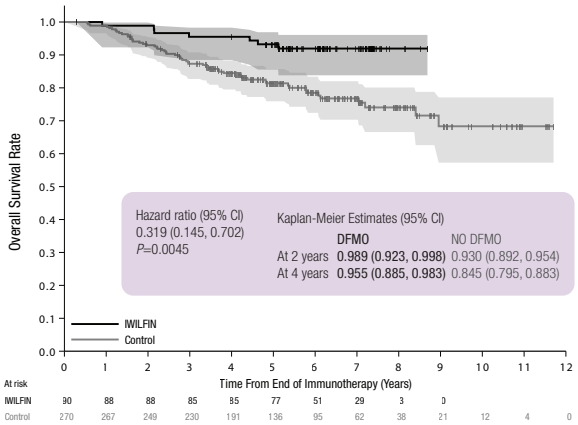


68% reduction in the risk of death with IWILFIN

Secondary Endpoint: OS

OS is defined as the first day of administration of IWILFIN until death due to any cause.

In supplementary analyses, the reduced risk of death for patients taking IWILFIN ranged from 71% to 55%.



IMPORTANT SAFETY INFORMATION (CONT'D)

IWILFIN can cause fetal harm. Advise females of reproductive potential of the possible risk to a fetus and to use effective contraception.

Safety Profile

IWILFIN offers an established safety profile with manageable side effects[1]

Of 360 patients with high-risk neuroblastoma who received IWILFIN as maintenance therapy in clinical studies, IWILFIN was generally well tolerated

Adverse reaction rates (≥5%) in patients who received IWILFIN in a pooled safety population (n=360)

Adverse Reaction	All Grades (%)
Hearing loss	11
Otitis media	10
Pyrexia	7
Pneumonia	5
Diarrhea	5

Most common (≥2%) grade 3 or 4 laboratory abnormalities (n=360)

Laboratory Abnormality	(%)
Increased ALT	11
Increased AST	6
Decreased neutrophils	4.2
Decreased hemoglobin	3.3

ALT, alanine aminotransferase; AST, aspartate aminotransferase.

- **Myelosuppression:** Monitor blood counts before and during treatment with IWILFIN. Withhold, reduce dose, or permanently discontinue based on severity
- **Hepatotoxicity:** Monitor liver function tests before and during treatment with IWILFIN. Withhold, reduce dose, or permanently discontinue based on severity
- **Hearing Loss:** Monitor hearing before and during treatment with IWILFIN. Withhold, reduce dose, or permanently discontinue based on severity
- **Embryo-Fetal Toxicity:** IWILFIN can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception

Based on the severity of adverse reactions to IWILFIN, reduce the patient's dose or stop treatment until the reaction subsides or resolves to baseline[1]. Please see recommended dose reductions contained in the Prescribing Information.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.

Dosage and Administration

IWILFIN is an oral tablet taken twice daily for 2 years

(or until recurrence of disease or unacceptable toxicity)[1]

Recommended dosage: 1 to 4 tablets based on BSA

BSA (m^2)	Dosage
>1.5	768 mg (4 tablets) orally twice a day
0.75 to 1.5	576 mg (3 tablets) orally twice a day
0.5 to <0.75	384 mg (2 tablets) orally twice a day
0.25 to <0.5	192 mg (1 tablets) orally twice a day

BSA should be evaluated every 3 months from initiation of dosing and throughout the duration of treatment to determine if a dose adjustment is needed.

Flexible Administration and Storage[1]

- IWILFIN may be swallowed whole, chewed, or crushed then mixed with soft food or liquid
- IWILFIN can be taken with or without food
- Store at room temperature, 68°F-77°F, with excursions permitted between 59°F-86°F

IWILFIN is available as 192-mg round, white to off-white tablets imprinted with EFL on one side and 192 on the other side. Actual size is ~11 mm in diameter.

BSA, body surface area ; EFL, eflornithine.

IMPORTANT SAFETY INFORMATION (CONT'D)

Adverse Reactions

The most common (≥5%) adverse reactions are hearing loss, otitis media, pyrexia, pneumonia, and diarrhea.

The most common (≥2%) Grade 3 or 4 laboratory abnormalities are increased ALT, increased AST, decreased neutrophil count, and decreased hemoglobin.

Getting your patients started with IWILFIN

IWILFIN Cares™ provides comprehensive support services to help your patients start and stay on therapy.

iwilfin™ CARES

IWILFIN Cares support services include:

Insurance Coverage Determination
A Support Specialist will work closely with you and your patient to determine their insurance coverage for IWILFIN.

Financial Support Eligibility
If your patient needs assistance paying for IWILFIN, a Support Specialist will share financial support options for which they may be eligible.

Coordinated Home Delivery
Once your patient's prescription is approved, our specialty pharmacy conveniently ships IWILFIN straight to their doorstep, proactively manages refills, and provides 24/7 pharmacist access.

For more information, go to IWILFIN.com or call 877-IWILFIN (494-5346) and select Option 1.

Prescribing is as easy as 1-2-3

1. Download the Referral Form from IWILFIN.com
2. Complete and sign the Referral Form
3. Fax the Referral Form to the number listed on the form

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.

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52% reduction in the risk of relapse
In an externally controlled clinical study, patients taking IWILFIN experienced a 52% reduction in the risk of relapse of high-risk neuroblastoma and a 68% reduction in the risk of death[1]

Convenient home use
The recommended dosage of IWILFIN is 1 to 4 tablets, based on BSA, taken twice daily at home or wherever is convenient[1]

Established safety profile with manageable side effects
The most common (≥5%) adverse reactions were hearing loss (11%), otitis media (10%), pyrexia (7%), pneumonia (5%), and diarrhea (5%)[1]

The most common (≥2%) Grade 3 or 4 laboratory abnormalities were increased ALT (11%), increased AST (6%), decreased neutrophil count (4.2%), and decreased hemoglobin (3.3%)[1]

To help protect your pediatric patients with high-risk neuroblastoma from relapse, consider prescribing IWILFIN.

References: 1. IWILFIN. Prescribing information. USWM, LLC; 2023 **2.** Data on file. USWM, LLC.

IMPORTANT SAFETY INFORMATION (CONT'D)

Warnings and Precautions
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