



# **PURIXAN<sup>®</sup>** (mercaptopurine) oral suspension



**FLEXIBLE**

**ACCURATE**



*Exactly what ALL\* patients need.*



**CONSISTENT**



**FDA APPROVED**



\*Acute lymphoblastic leukemia.  
Please refer to the enclosed package insert for full prescribing information.



# **PURIXAN<sup>®</sup>** *(mercaptopurine) oral suspension*

## **What is PURIXAN?**

PURIXAN (mercaptopurine) oral suspension is indicated for the treatment of patients with acute lymphoblastic leukemia (ALL) as part of a combination regimen.<sup>†</sup>

PURIXAN is a liquid alternative to the mercaptopurine tablet.

## **Why PURIXAN?**

Accurate Dosing within 2 mg

Flexible Dosing<sup>3</sup>

Single Daily Dose<sup>†</sup>

Consistent Absorption<sup>3</sup>

Predictable Performance<sup>3</sup>

Better Tasting Medicines Make Adherence Easier in Children<sup>1,5,6</sup>

Only FDA-approved Mercaptopurine Oral Suspension

Easy to Order: 1-888-470-0904





59% of all relapses in children are attributable to nonadherence<sup>9</sup>

## NONADHERENCE TO MERCAPTOPYRINE RESULTS IN RELAPSE FOR CHILDREN<sup>9,10,11</sup>



Until 2014, the only marketed formulation of mercaptopurine has been a 50 mg tablet<sup>3</sup>

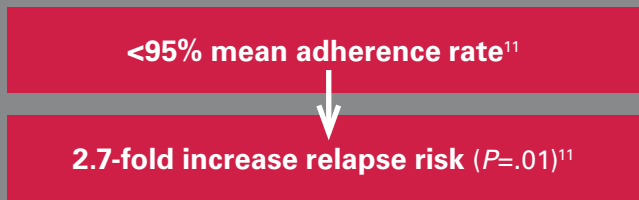
Fixed doses are impractical because the dose varies according to the size of the child.<sup>1</sup>

Fewer than 10% of children receive a 50 mg tablet (or a multiple of 50 mg) as a daily dose.<sup>2</sup>

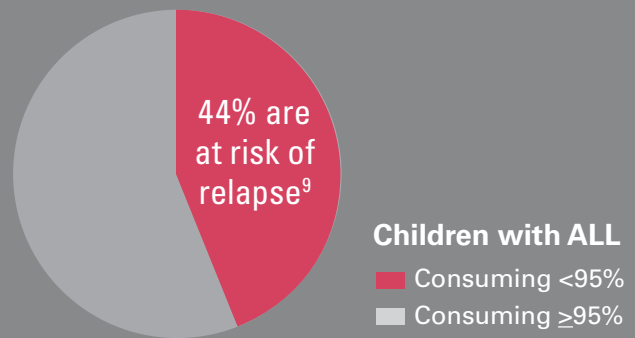
### NONADHERENT CHILDREN

Children with mercaptopurine mean adherence rates <95% are at a 2.7-fold increased risk of relapse compared to patients with mean adherence rates of 95% or greater ( $P=.01$ ).<sup>11</sup>

Mercaptopurine adherence and steady thiopurine exposure minimize relapse in children.<sup>11</sup>



44% of children with ALL\* are consuming <95% of prescribed mercaptopurine and are consequently at risk of relapse.<sup>9</sup>



### ADHERENT CHILDREN

Among adherers, high intra-individual variability in TGN\*\* levels contributed to a 4.4-fold increased relapse risk. ( $P=.02$ )<sup>11</sup>

Adherers with varying TGN levels were more likely to have varying mercaptopurine dose intensity and mercaptopurine drug interruptions.<sup>11</sup>



\*Acute lymphoblastic leukemia. \*\*Erythrocyte thioguanine nucleotide. Please refer to the enclosed package insert for full prescribing information.



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## PALATABILITY AND ACCEPTABILITY

Better tasting medicines make adherence easier in children<sup>1,5,6</sup>

PURIXAN has a pleasant raspberry flavor and is in a liquid form, which makes it much easier for most children to swallow than a tablet.<sup>1,5</sup>

In a study assessing the palatability of PURIXAN in children with ALL<sup>5</sup>:

- √ 82% report PURIXAN is **easy to take all the time**
- √ 77% of children rank PURIXAN's **taste ok to good**
- √ 91% of children rank PURIXAN's **smell ok to good**



## EASY TO ORDER

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## CONSISTENT ABSORPTION

PURIXAN reduced the variability in the absorption of mercaptopurine, proving itself to be a dependable and reliable alternative to the tablet.<sup>3</sup>

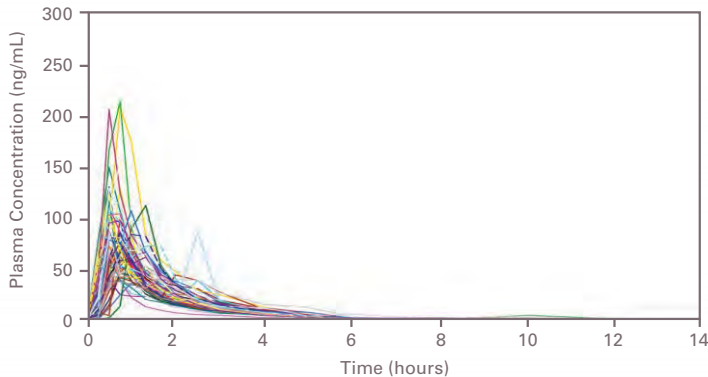
## PREDICTABLE PERFORMANCE

PURIXAN performs more consistently and predictably than the mercaptopurine tablet.<sup>3</sup>

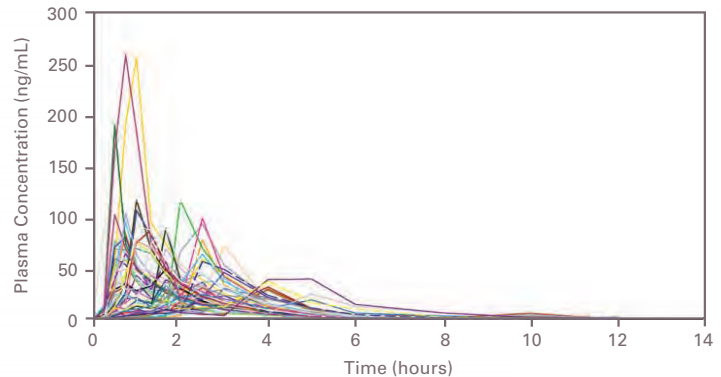
In contrast, splitting a mercaptopurine tablet produces an inaccurate dose, further reducing consistency and predictability.<sup>3</sup>

PURIXAN had substantially lower between-subject variability in maximum plasma concentrations (46% vs 69% coefficient of variation).<sup>3</sup>

**Individual Plasma Concentration Profiles (n=60) of Mercaptopurine Following a Single 50-mg Dose of PURIXAN Oral Suspension**



**Individual Plasma Concentration Profiles (n=60) of Mercaptopurine Following a Single 50-mg Dose Tablet<sup>3</sup>**



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## FLEXIBLE & ACCURATE DOSING

PURIXAN 20 mg/mL oral suspension can be accurately dosed down to 2 mg (0.1 mL) providing an opportunity to administer mercaptopurine in a way that may be more acceptable to children.<sup>1,4,6</sup>

**Mercaptopurine Doses Individualized to Body Surface Area (BSA)**

Age	BSA (m <sup>2</sup> ) <sup>a</sup>	Dose (mg)	Volume (mL)
3 months	0.27-0.33	20-25	1.0-1.3
1 year	0.47-0.53	35-40	1.8-2.0
3 years	0.61-0.67	46-50	2.3-2.5
5 years	0.74-0.79	56-59	2.8-3.0
10 years	1.07-1.13	80-85	4.0-4.3
12 years	1.27-1.83	95-100	4.8-5.0
18 years	1.77-1.83	133-137	6.7-6.9

<sup>a</sup>Based on WHO growth charts for children (may not correspond to the BSA of individual patients).<sup>7</sup> <sup>b</sup>Based on a typical starting dose of 75 mg/m<sup>2</sup>.<sup>8</sup>

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## Warnings and Precautions<sup>†</sup>

### Myelosuppression

The most consistent, dose-related toxicity of PURIXAN is bone marrow suppression.

### Hepatotoxicity

Mercaptopurine is hepatotoxic. There are reports of deaths attributed to hepatic necrosis associated with the administration of mercaptopurine. Hepatic injury can occur with any dosage, but seems to occur with greater frequency when the recommended dosage is exceeded.

### Immunosuppression

Mercaptopurine is immunosuppressive and may impair the immune response to infectious agents or vaccines.

### Embryo-Fetal Toxicity

PURIXAN can cause fetal harm when administered to a pregnant woman. If this drug is used during pregnancy or if the patient becomes pregnant while taking the drug, the patient should be apprised of the potential hazard to a fetus.

### Treatment-Related Malignancies

Cases of hepatosplenic T-cell lymphoma have been reported in patients treated with mercaptopurine for inflammatory bowel disease (IBD), an unapproved use.

A treatment regimen containing multiple immunosuppressants (including thiopurines) should be used with caution as this could lead to lymphoproliferative disorders, some with reported fatalities. A combination of multiple immunosuppressants, given concomitantly increases the risk of Epstein-Barr virus (EBV)-associated lymphoproliferative disorders.

### Macrophage Activation Syndrome

Macrophage activation syndrome (MAS) (hemophagocytic lymphohistiocytosis) is a known, life-threatening disorder that may develop in patients with autoimmune conditions, in particular with inflammatory bowel disease (IBD), and there could potentially be an increased susceptibility for developing the condition with the use of mercaptopurine (an unapproved use).

### Laboratory Tests

Monitor the following laboratory tests in patients receiving PURIXAN: Complete blood counts (CBCs), transaminases, and bilirubin. Evaluate the bone marrow in patients with prolonged or repeated marrow suppression to assess leukemia status and marrow cellularity.

## Adverse Reactions<sup>†</sup>

Adverse Reaction	Occurrence in ALL Trials (%)
Myelosuppression: Including anemia, neutropenia, lymphopenia, and thrombocytopenia	>20
Anorexia, nausea, vomiting, diarrhea, malaise, and rash	5 to 20
Urticaria, hyperuricemia, oral lesions <sup>a</sup> , elevated transaminases, hyperbilirubinemia, hyperpigmentation, and pancreatitis	<5
Delayed or Late Toxicities: Including hepatic fibrosis, hyperbilirubinemia, alopecia, pulmonary fibrosis, oligospermia, and secondary malignancies	

<sup>a</sup>Oral lesions resemble thrush rather than antifolic ulcerations

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<sup>†</sup>Please refer to the enclosed package insert for full prescribing information.



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PURIXAN Order Number: 1-888-470-0904

To report suspected adverse reactions, please call Rare Disease Therapeutics: 1-888-470-0578

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