Pharmacally.com

NEWSLETTER

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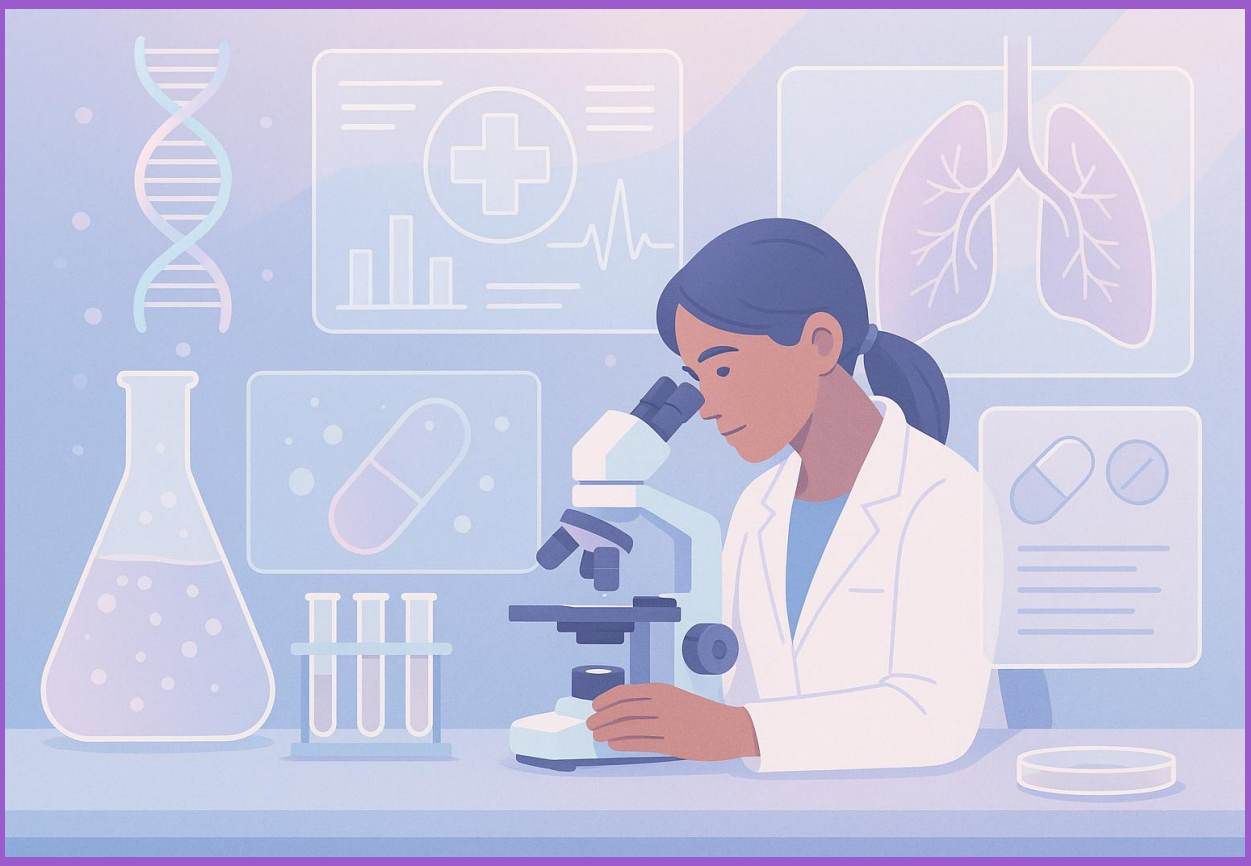
THERASPACE

Your Therapeutic Space for Smarter Health



The Official Newsletter of Pharmacally.com

Content In*Side*

Welcome to TheraSpace

Welcome to TheraSpace

Dear Reader,

Welcome to the very first issue of TheraSpace – the official newsletter of Pharmacally.com

In a world flooded with health information and AI is advancing, at one click a tons of information appears on the screen, but how accurate are they? Are they based on reliable sources? Who has validated them? The answers are often unclear. So our goal is simple yet powerful: to offer **curated, credible and current** medical knowledge that come from experienced health professionals and empowers your health knowledge and to some extent your decisions. Whether you're a healthcare professional, researcher, student, or just a curious mind; TheraSpace is designed to be your trusted companion on the journey of modern healing.

At Pharmacally, we believe that smarter health choices stem from a deeper understanding of medicine across disciplines, systems, and timelines. With TheraSpace, we bring you closer to the future of healthcare, one discovery at a time.

Warm regards,
Pharmacally.com

Vision of TheraSpace

In today's rapidly advancing medical world, revolutionary therapies, technologies, and scientific insights are emerging every day. But much of this knowledge remains inaccessible to the public; buried under complex jargon, dense research papers, or pay walled journals.

TheraSpace was created to change that.

The name **TheraSpace** stands for **"Therapeutic Space."**

Therapeutic signifies healing the powerful effect that medical knowledge, innovation, and intervention can have on the human body and mind.

Space represents your personal zone of reflection a calm corner of your busy life where you can pause, explore, and understand the science shaping the future of health.

Together, TheraSpace becomes **your personal healing space** where modern medicine meets mindful awareness.

Our vision is to bridge the gap between cutting-edge clinical science and public understanding by simplifying complex data into clear, practical, and reader-friendly content**.** Whether it's a new drug approval, a breakthrough clinical trial, or an ancient remedy with modern evidence, *TheraSpace* makes it approachable, relevant, and actionable.

We're here to make you *feel smarter about health*, with or without needing a medical degree.

With every issue, TheraSpace invites you to stay curious, stay informed, and stay empowered.

Revolutionizing Diabetes: Once-Weekly Insulin Icodec Outperforms Daily Regimens

Summary:

A landmark Phase III trial, part of the ONWARDS program, evaluated Insulin Icodec the world's first once-weekly basal insulin against daily insulin glargine. The trial demonstrated that Icodec achieved greater HbA1c reduction, similar safety, and comparable hypoglycaemia rates. It simplifies diabetes management without sacrificing effectiveness

A pivotal Phase III trial, published in the *New England Journal of Medicine*, compared **Insulin Icodec** (a once-weekly basal insulin) to once-daily insulin glargine U100 in people with type 2 diabetes who were insulin-naïve

ONWARDS Trial Highlights

ONWARDS 1–6 Trials: Enrolled over 4,000 patients globally

Key Results:

- ↓ Greater HbA1c reduction vs. daily Glargine
- ↔ Comparable hypoglycaemia risk
- ✔ High patient satisfaction & adherence rates

Population: Adults with type 2 (and some with type 1) diabetes

Duration: 26–52 weeks

Primary Endpoint: Change in HbA1c at 26 weeks

These trials form the backbone of current regulatory submissions and future global rollout.

Key findings over 52 weeks:

HbA1c reduction: From 8.50% to 6.93% with Icodec vs. 8.44% to 7.12% with Glargine (mean change −1.55 pp vs. −1.35 pp); Icodec proved noninferior and even marginally superior (difference −0.19 pp; P=0.02)

Time in range: (70–180 mg/dL): Higher with Icodec (71.9% vs. 66.9%; +4.27 pp; P<0.001)

Hypoglycaemia rates: Clinically significant or severe hypoglycaemia occurred at rates of 0.30 vs. 0.16 events per person-year (Icodec vs. Glargine) at week 52; not statistically different

Safety and adverse events: Comparable between groups, with no new concerns

Impact on Public Health

Easier regimen better adherence and fewer missed doses

Less injection anxiety, especially for elderly and youth

Improves care in remote or under-resourced regions

Reduces system burden, fewer visits, easier monitoring

Scalable innovation for diabetes programs worldwide

"Moving from 365 to 52 injections a year could redefine how we think about insulin adherence." — Endocrinology Thought Leader

Global Approval Timeline of Insulin Icodec (Awiqli®)

Country/Region	Status	Date Approved
Switzerland	Approved for type 1 & 2	March 7, 2024
Canada	Approved for adult use	March 12, 2024
European Union	Full EU approval	May 17, 2024
Australia	Approved for type 1 & 2	May 2024
Japan	Approved for type 2	Mid 2024
China	Approved (only type 2)	Mid 2024
USA	Not yet approved (CRL issued)	Pending (FDA CRL - Jul 2024)

U.S. FDA issued a **Complete Response Letter (CRL)** in July 2024, citing manufacturing and type 1 data concerns. Approval for **type 2 diabetes** is still expected by **mid-to-late 2025**.

Sulenca and Yeztugo (Lenacapavir): A Biannual Injection for HIV Prevention and Treatment

Summary

Sulenca and Yeztugo (brand names for lenacapavir) is a long-acting capsid inhibitor administered via subcutaneous injection every six months. While initially approved in December 2022 by the FDA for treating multi–drug-resistant HIV-1, recent Phase III PrEP trials demonstrate its breakthrough potential in prevention

PURPOSE 2 Trial (Men & Gender-diverse individuals) – Published in *New England Journal of Medicine*, this global study compared biannual lenacapavir injections (plus oral dose) to daily oral emtricitabine/tenofovir (Truvada). Among 3,265 participants, just 2 new HIV infections occurred in the lenacapavir group (0.10/100 person-years) versus 9 infections in the Truvada group (0.93/100 person-years). This represents a 96% reduction in HIV incidence.

PURPOSE 1 Trial (Cisgender women) – An interim analysis showed zero HIV cases among 2,134 participants on biannual injections, compared to multiple infections in the Truvada/Descovy arms, demonstrating clear superiority (100% efficacy in this cohort).

Safety & Tolerability- Injection-site reactions occurred, but only 1.2% discontinued due to them. Nausea affected ~4%. No major systemic issues reported.

PURPOSE Trials Highlights

Trial	Population	Key Outcome
PURPOSE 1	Cisgender women (Africa)	100% efficacy — 0 new HIV cases
PURPOSE 2	MSM & gender-diverse (global)	96% reduction vs. Truvada
Duration	Up to 52 weeks	Long-term protection with 2 annual shots
Safety	Injection site issues (mild, rare)	1.2% discontinued due to local reactions

> *"Lenacapavir could be the most transformative HIV prevention tool we've ever seen." — Infectious Disease Expert*

Public Health Impact

Adherence Simplified: Reduces pill burden and potential of reducing missed doses twice a year shots are

Game-changing for populations with low daily adherence.

Expands Access: Ideal for underserved, stigmatized, or mobile populations who struggle with routine

Stigma Reduction: Fewer clinic visits mean more privacy and autonomy.

"Vaccine-like" Protection: High efficacy with minimal dosing—UNAIDS noted this could be *"closest we've come to a vaccine,"* as reflected by leaders in the field

Equity Caveat: Cost and roll-out in low-resource settings will require licensing efforts and pricing strategies to avoid deep inequities

Regulatory & Approval Timeline for Sulenca (Lenacapavir)

Region	Use Approved	Date
USA	Treatment of MDR HIV-1	Dec 2022
Global Trials	Prevention (PrEP), Completed	2023–2025
USA	FDA Priority Review for PrEP use	Feb 2025
USA	FDA decision for PrEP	June 18, 2025

Regulatory filings for prevention use are in progress in Europe, South Africa, and Brazil.

Scan and Read the full article at Pharmacally.com

Novel Drugs Approval in First Half of 2025

The first half of 2025 has seen a wave of novel treatments approved by the FDA and EMA, many of which are already transforming lives. Here are the top therapeutic breakthroughs with clear benefits for patients and providers alike.

Ibtrozi (Taletrectinib)

A Precision Therapy for Rare Lung Cancer

Indication

ROS1-positive non-small cell lung cancer (NSCLC) — a rare subtype affecting 2% of lung cancer patients, often younger, non-smoking individuals

Mechanism of Action

A **ROS1 tyrosine kinase inhibitor** that selectively targets gene fusions driving tumor growth. Designed to overcome resistance seen with earlier drugs like crizotinib

Clinical Basis for Approval

Based on data from TRUST and TRUST-II trials in Asia and globally, showing ORR (Objective Response **Rate):** 78% in treatment-naïve patients. Intracranial response**:** Demonstrated efficacy in patients with brain metastases. Well tolerated with mostly mild gastrointestinal or liver-related AEs

> *"With Ibtrozi, we're seeing response rates that change the outlook for a niche, high-need group of patients." – Lead TRUST-II Investigator*

Approval Status

- FDA Approval**:** ✓ June 11, 2025
- For Whom: Adults with locally advanced or metastatic ROS1-positive NSCLC
- Regulatory Designations: Orphan Drug & Breakthrough Therapy

Patient Impact

- Provides a highly effective, targeted oral therapy for a rare lung cancer subset
- Reduces brain metastasis risk and progression
- Offers hope for longer survival in a population that often relapses on older drugs

Zusduri (Mitomycin)

A New Hope for Bladder Cancer Recurrence Prevention

Indication

Non–muscle-invasive bladder cancer (NMIBC) — specifically in adults with **low-grade, intermediate-risk** disease that often recurs after surgery

Mechanism of Action

Zusduri is a sustained-release intravesical chemotherapy gel containing mitomycin**,** designed to **adhere to the** bladder wall and release medication gradually over time

Clinical Basis for Approval

Approved based on the ATLAS trial**,** showing:

- Significant reduction in tumor recurrence vs. historical controls
- Improved dwell time in the bladder, enhancing chemotherapy exposure
- Administered via outpatient catheter; non-invasive and well tolerated
- Side effects limited to mild urinary irritation and bladder discomfort

> *"Zusduri turns a high-recurrence condition into a manageable disease." — Urologic Oncologist, ATLAS Trial*

Approval Status

- FDA Approval**:** ✅ June 12, 2025
- For Whom**:** Adults with low-grade NMIBC who have previously undergone transurethral resection
- Submission to EMA expected by Q3 2025

Patient Impact

- Reduces the need for repeat surgeries**,** which are common in NMIBC
- Enhances bladder preservation strategies
- Improves patient quality of life and reduces hospital visits

Gomekli (Mirdametinib)

First-Ever Oral Therapy for NF1-Related Tumors

Indication

Neurofibromatosis Type 1 (NF1)-associated inoperable Plexiform Neurofibromas — typically affects children and young adults, causing painful, disfiguring, and function-impairing tumors.

Mechanism of Action

Mirdametinib is a selective MEK1/2 inhibitor that blocks the RAS/MAPK signalling pathway, which is hyperactive in NF1. This reduces tumor size and halts further progression.

Clinical Basis for Approval

Based on the SPRAY trial, a Phase II/III study showing:

- Tumor shrinkage ≥20% in 68% of pediatric patients
- Pain reduction and improved mobility in daily life
- Long-term tolerability with most common AEs: acneiform rash, GI upset, fatigue

> *"My son can now play, run, and laugh again without pain. Gomekli gave us back our everyday life." — Parent from SPRAY trial*

Approval Status

- FDA Approval: ✓ February 11, 2025
- EMA Submission: Under review as of May 2025
- For Whom: Pediatric and adult patients (aged ≥2) with symptomatic, inoperable Plexiform Neurofibromas

Patient Impact

- First approved medical treatment for a historically untreatable tumor type
- Avoids or delays high-risk surgeries
- Improves mobility, pain control, and emotional well-being for children and their families

Unique Case Study

Infant 'KJ' Healed with Personalized CRISPR-Cas9 for CPS1 Deficiency

Summary

In February 2025, a team at the Children's Hospital of Philadelphia (CHOP) and Penn Medicine delivered the world's first in vivo personalized CRISPR gene-editing therapy to a six-month-old infant, KJ, born with **severe** carbamoyl phosphate synthetase 1 (CPS1) deficiency**,** a rare urea cycle disorder causing toxic ammonia buildup which may leads to death.

Clinical Insight

- The treatment was custom-designed for KJ's specific genetic mutation.
- Delivered via lipid nanoparticle-based system targeting the liver**,** using base editing (not full genome cuts), offering greater precision
- Outcome: KJ no longer required strict ammonia-lowering diet or transplant; is growing and thriving, with safe follow-up infusions

Learning Point

This landmark case illustrates the feasibility of ultra-personalized in vivo gene editing designed and deployed in just six months ushering in a new era where therapies target individual mutation profiles rather than broad populations

Broader Impact

- Breaks fresh ground for treating ultra-rare genetic disorders previously deemed untreatable.
- Demonstrates rapid development pipelines leveraging CRISPR and lipid nanoparticles.
- Sets a precedent for nimble "N-of-1" therapy models, blending research and care seamlessly.
- Ethical & long-term follow-up remain crucial, but this case offers hope for scalable personalized medicine

Key Innovation Takeaways

- **Base editing** offers a safer, precise alternative to double-strand DNA cutting.
- **Lipid nanoparticle delivery** staples systemically reach the liver—ready for broader disease applications.
- The "from gene discovery to dosing in six months" timeline signals a revolution in **therapeutic agility**.
- **Ethical oversight and long-term studies** are vital as we transition from trials to scalable treatments.

Scan the QR to read full article

Drug Safety Alerts

1) Chikungunya Vaccine (Ixchiq) – Safety Alert

Who is affected?

Adults aged 60 years and older using the live-attenuated chikungunya vaccine, **Ixchiq** (by Valneva).

What happened?

As of May 7, 2025, 17 serious adverse events including two deaths (one from encephalitis, one from aspiration pneumonia) have been reported in individuals aged 62–89 years globally, six of which occurred in the U.S. Most had chronic comorbidities

Regulatory action:

The FDA and CDC jointly recommended pausing use among adults ≥60 years while post-marketing safety is assessed

The European Medicines Agency (EMA) has restricted use in those ≥65 years pending review

The UK's MHRA also suspended use in ≥65 year-olds

Clinical implications

Indicated for adults aged 18–59 only, the vaccine remains permitted, especially in regions with active chikungunya outbreaks but should not be administered to individuals ≥60 years until further guidance is issued.

2) Counterfeit Herceptin® in Ghana – Urgent Warning

What's the concern?

The Ghana FDA has confirmed circulation of **counterfeit** Herceptin® (trastuzumab 600 mg/5 mL, batch **A8519**) in Kumasi, Ghana. The fake vials do not match any legitimate Roche batch

Ripple effect:

The counterfeit product was reportedly originally procured from **Nigeria**, with distribution reaching Ghana

Patient risk

Individuals receiving this product may experience treatment failure due to lack of active drug or **severe** unknown toxicities potentially risking cancer progression or harmful side effects

Recommended actions

Healthcare providers: Source trastuzumab from **authorized suppliers**; carefully verify batch numbers, seals, and packaging.

Patients: Report any adverse reactions or ineffective cancer treatment promptly. **Notify** health authorities if suspect counterfeit is identified.

Regulators: Intensify surveillance, seize fake stock, and educate the public on verifying genuine oncology products.

3) Transderm Scōp (Scopolamine Patch) – Heat-Related Risk Alert

Who is at risk?

Patients under 18 years using it off-label (e.g., for drooling) and older adults 60 years and above groups particularly susceptible to impaired temperature regulation

What's the concern?

The FDA has added a new label warning after reviewing 13 reported cases of hyperthermia linked to scopolamine patches, with 12 resulting in serious outcomes 6 hospitalizations and 2 deaths (one in a child, one in an older adult). Symptoms typically emerged within 72 hours of the first patch application, often worsened by warm environments or external heat sources like heated blankets

Labelling changes

The prescribing information now includes an explicit heat-related risk warning, along with recommendations to avoid external heat and to monitor closely during the initial 3-day period post-application

1) Breakthrough in Breath: Early Lung Cancer Detection via VOC Analysis

A non-invasive breath test achieves over 96% accuracy in detecting early-stage lung cancer using cutting-edge HPPI-TOFMS technology

The Innovation

In a world-first clinical study published in the *Journal of Clinical Oncology* (Vol. 38, 15_suppl), researchers from China led by Mantang Qiu and colleagues have demonstrated the power of a breath-based diagnostic test for detecting early-stage lung cancer, leveraging high-resolution High-Pressure Photon Ionization Time-of-Flight Mass Spectrometry (HPPI-TOFMS).

How It Works

The test analyzes volatile organic compounds (VOCs)—tiny gas molecules exhaled through breath, produced by cellular metabolic processes that can reflect disease states, including cancer. Here's how the study was designed

Who was studied?

171 treatment-naive patients with pulmonary nodules, all undergoing surgery. Of these, 139 were confirmed to have lung cancer (114 in **Stage I**) and 32 had benign nodules.

How samples were collected

Breath was collected pre-surgery using Tedlar bags**,** ensuring alveolar air capture via CO_2 sensor guidance for sample purity.

How it was tested

Samples were immediately analyzed by HPPI-TOFMS — a high-resolution, rapid mass spectrometry platform capable of profiling >32,500 features per breath**.**
A deep learning model trained on these profiles was used to classify samples.

Results That Matter

- **Accuracy:** 96.19%
- **Sensitivity:** 96.43%
- **Specificity:** 84.38%
- **Metastasis discrimination:** 83.23% accuracy between patients with vs. without lymph node involvement

These figures outperform many traditional diagnostic methods and could revolutionize early detection strategies

Why This Matters

- **Non-invasive:** No radiation, blood draws, or biopsies
- **Accessible:** Potentially deployable in outpatient clinics or mobile vans
- **Efficient:** Near-instant analysis using breath—a sample you can collect in seconds

Early detection is crucial in lung cancer**,** which is often diagnosed late due to subtle symptoms. With this breath test, detecting Stage I tumors becomes a realistic goal offering patients better prognosis and more treatment options.

2) Sweat as a Signal: Real-Time Health Tracking via Wearable Sweat-Sensing Patches

Flexible, skin-safe biosensors are turning sweat into a powerful diagnostic tool for chronic and real-time health monitoring.

The Innovation

A comprehensive review published in *Sensors and Actuators Reports* sheds light on a new frontier in non-invasive diagnostics: Wearable Sweat-Sensing Patches (WSPs)**.** These compact, multilayer devices are designed to continuously monitor physiological biomarkers—like glucose, electrolytes, pH, lactate, and hormones through trace amounts of sweat, making them ideal for chronic care, athletic recovery**,** and remote health surveillance**.**

How It Works

WSPs are built on biocompatible, flexible substrates with three integrated layers:

- **Adhesive Layer:** Medical-grade materials such as PDMS ensure skin-safe, long-term attachment.
- **Sampling Layer:** Hydrophilic or porous polymers guide sweat to the detection zone using microfluidics.
- **Sensing Layer:** Graphene, metal nanoparticles, or conductive polymers embedded with enzymes or antibodies enable **electrochemical, colorimetric, or impedance-based detection.**

Key Insights

- Sweat, though less concentrated than blood, offers continuous access to biomarkers with no puncture required.
- Innovations in microfluidics reduce evaporation and contamination, improving result reliability

IoT integration enables real-time data upload and AI-powered analytics for personalized trends and early alerts.

Why This Matters

- **Painless and portable:** No needles, no lab work—just apply and monitor.
- **Prevention-first mindset:** Continuous data helps detect dehydration, glucose spikes, electrolyte imbalances, or stress changes *before symptoms arise*.
- **Scalable health tech:** Potential for remote disease monitoring, elder care, fitness optimization, and even mental health tracking (via cortisol and pH sensors).

What's Next

The path forward includes:

- Self-powered patches (energy from body heat/sweat)
- Closed-loop systems that trigger interventions automatically
- Full integration into telemedicine**,** wearable, and sports gear

As WSPs transition from lab to lifestyle, they offer a groundbreaking shift from reactive treatment to proactive health management.

From the Roots-Traditional Medicine

Guduchi (Tinospora Cordifolia): The Ayurvedic Elixir with Modern Promise

Guduchi, also known as Giloy or Gulvel, is a revered herb in Ayurveda, celebrated for its rejuvenating and immune-enhancing qualities. Termed “Amrita” or “nectar of immortality,” this climbing shrub is now attracting significant attention from modern pharmacology for its diverse therapeutic potential.

Key Evidence-Backed Health Benefits

- **Immune Modulation:** Guduchi boosts immune activity by stimulating key cytokines like IFN-γ and TNF-α supporting its wide use during the COVID-19 pandemic.
- **Anti-inflammatory & Antipyretic:** Extracts have shown effects comparable to paracetamol and diclofenac in preclinical models.
- **Metabolic Support:** While some data confirm its mild hypoglycemic action, other studies suggest improved insulin sensitivity and protection against diabetes-related complications.
- **Liver Protection:** Guduchi Satva formulations have shown hepatoprotective benefits, especially in alcohol- or drug-induced liver injuries.
- **Respiratory & Viral Defense:** Guduchighana Vati improved outcomes in COVID-19 trials, with faster viral clearance and symptom recovery.
- **Autoimmune Modulation:** Studies in arthritis models showed suppression of inflammatory markers and joint preservation.
- **Cardiovascular Benefits:** Animal studies reveal improvements in cholesterol profiles and reduced atherosclerotic risks.

Available Forms

Capsules, decoctions (Kadha), Guduchi Satva (dry extract), juice, and topical applications

Safety Note

Generally recognized as safe, but high doses or long-term use should be monitored in patients with liver disorders, autoimmune conditions, or those on immunosuppressant

Guduchi exemplifies how traditional medicine is being validated by modern science. With its broad therapeutic effects from immunity and metabolism to liver and joint health Guduchi stands as a promising candidate in integrative and preventive care.

Scan the QR to read full article

From the Editor's Desk

As we wrap up this inaugural issue of TheraSpace, thank you for joining us in exploring the evolving world of medicine, healing, and discovery. Our mission remains clear: to bridge the gap between advanced medical science and your everyday health understanding.

We hope this issue leaves you more informed, empowered, and inspired to stay curious. We look forward to bringing you more groundbreaking insights in the next edition.

— Team Pharmacally

We'd Love to Hear From You!

Have feedback, topic ideas, or a story to share?

Email us: contactus@pharmacally.com

Visit: www.pharmacally.com

Share this newsletter with your colleagues, peers, and curious minds who want to stay ahead in healthcare.

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Pharmacally.com is an independent health information platform dedicated to simplifying complex science. We publish current, evidence-based content on therapeutics, diagnostics, traditional medicine, and innovations with a clear goal: make smarter health accessible to all.

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Final Thought

"Every cure begins with understanding."

Stay informed. Stay inspired. Stay well.

Pharmacally

Advancing Medical Communication for a Healthier and Safer Future

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