

# The Pharma Jukebox

VOLUME 1, ISSUE 3 | AUGUST, 2011 NEWSLETTER

*"Own the RESPONSIBILITY to change for the betterment of ourselves and the Society."*

*-Vishal Jajodia  
CEO*

From the editor's desk:

The Orphan Drug Act has proved a piece of legislation. Since its enactment some 282 orphan drugs have been marketed, providing treatment for more than 14 million patients in the US. Many more rare diseases are eagerly awaiting their treatment.

Orphan diseases do not attract much attention, research or funding, simply because they are extremely rare and poorly publicized. The vision of Mr. Vishal Jajodia (CEO, Swati Spentose Pvt. Ltd), is to create a historic benchmark by bringing to market new health solutions with old orphan molecules like Pentosan in line with our social commitment to concentrate on neglected diseases.

This issue of The Pharma Jukebox rotates around Orphan Drugs and how Pentosan made its way into the league of Orphan Drugs.

We would like to hear from you.

Sanaa Jummal  
Editor

Feedback At:

Email: [pr@spentose.com](mailto:pr@spentose.com)

Contact Details:  
+91- 22- 61505208



## Orphan Drug Act: A "Messiah" for pharmaceutical companies...

*You see things; and you say,*

*"Why?"*

*But I dream things that never*

*were; and I say,*

*"Why Not?"*

*-George Bernard Shaw*

In order to understand the Orphan Drug Act (ODA), one needs to comprehend with what an Orphan Drug is. An Orphan Drug status is granted to certain drugs undergoing development by a pharmaceutical company for the treatment of rare diseases. The ODA was established by the FDA in 1983, which gives incentives to encourage pharmaceutical companies to work on cures for rare diseases.

Another incentive provided by the FDA for the development of an Orphan Drug to the pharmaceutical company developing it, is the grant of Orphan Drug status, even if the drug is currently failing to meet the standards for approval. However,

the goal behind this move was to provide incentive to the pharmaceutical company to continue the research, even when if the drug doesn't turn out to be the miracle cure it was initially thought off.

The story of zinc acetate for treatment of Wilson Disease, illustrates the development of an orphan drug. In the 1970's George J. Brewer, professor of human genetics and internal medicine at University of Michigan, was attempting to treat sickle cell anemia with orally administered zinc salts when he noticed that zinc salts were creating a deficiency of copper. This led to the discovery that zinc salts could prove beneficial in the treatment of Wilson disease, a disorder with a genetic error in copper metabolism.

Pentosan Polysulfate Sodium (PPS) follows a similar story for the treatment of Interstitial Cystitis (IC). PPS was granted

orphan drug status in the year 1996. It is the only FDA approved oral drug for the treatment of IC.

The prevalence rate of IC was rising constantly and with only one approved source, there was too much on stake for the patients and hence Swati Spentose Pvt Ltd. took the global initiative of bringing to market a cost effective alternate source with the facility approvable by global FDA's like USFDA, EQDM, Japanese FDA and alike.

For further details visit us at:

[www.comfora.in](http://www.comfora.in)  
[www.comforachemist.in](http://www.comforachemist.in)  
[www.spentose.in](http://www.spentose.in)

With our fully backward and forward integration facilities and collaboration with prestigious institutions across the world, we are making a mark for ourselves in the world of Orphan Molecules.

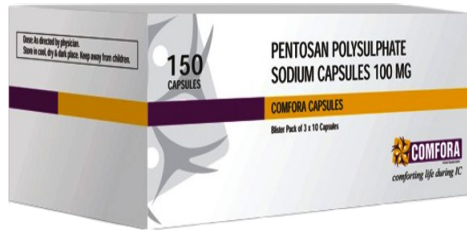
## SOMETHING ABOUT THE COMPANY:

Swati Spentose Pvt Ltd, is a subsidiary of the 40 year old Euresian group.

Swati Spentose has established unique-cutting edge technology platforms in the development of Polysaccharides bio-generics, in collaboration with world renowned research platforms like Mt Sinai School of Medicine and clinicians and scientists world over.

The key therapeutic areas of Swati Spentose include urology, chronic progressive vascular disease and diabetes among others.

*Our Basket of Finished Dosages:*



- **Anesthetic:**  
Anthacaine (Lidocaine)- Vial, Injection, Gel, Spray
- **Anti-Inflammatory:**  
Dflam (Dimethyl sulphoxide) - Vial, Gel, Cream

For a complete information on Finished Dosages contact [fd@spentose.com](mailto:fd@spentose.com)

- **Urology:**
  - I. Comfora (Pentosan Polysulfate sodium)- Capsules
  - II. Dutride T (Dutasteride & Tamsulosin HCl)- Capsules
  - III. Dutride (Dutasteride)- Capsules
  - IV. Terod (Tolterodine Tartrate) - Tablets
  - V. Finflow (Finasteride)- Tablets
  - VI. Tamysin (Tamsulosin)- Tablets

We offer following API's from USFDA, EDQM, UKMCA, TGA Australia, MCC-South Africa approvable site :

- Pentosan Polysulfate sodium
- Lidocaine HCl / Base
- Dextran Salts
- Meloxicam
- Hydroxyl Ethyl Starch
- Phenytoin Base / Sodium

For further information contact : [api@spentose.com](mailto:api@spentose.com)



**SWATI SPENTOSE PVT. LTD.**

114, Marine Chambers,  
11, New Marine Lines,  
Mumbai-400 020, India.

Tel-0091-22-66332427  
Fax-0091-22-22071955

For more information visit us at : [www.spentose.com](http://www.spentose.com)

Or Drop in a mail at [communications@spentose.com](mailto:communications@spentose.com)

Or Give us a call at the number mentioned to the left