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Vagitol advertisement.

[s.l.]: [s.n.], 1975

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NOTE:

If possible, base treatment on specific diagnoses from sound clinical and laboratory methods.

INDICATIONS

Based on review of this drug by the National Academy of Sciences—National Research Council and/or other information, FDA has classified the indications as follows:

† "Probably" effective: For the relief of symptoms of vulvovaginitis where isolation of the specific organism responsible (usually *Trichomonas vaginalis*, *Candida albicans*, or *Haemophilus vaginalis*) is not possible.

NOTE: When the offending organism is known, treatment with a specific agent known to be active against that microorganism is preferred.

"Possibly" effective: For the treatment of trichomoniasis, vulvovaginal candidiasis, and vaginitis due to *Haemophilus vaginalis* or other susceptible bacteria.

Final classification of the less-than-effective indications requires further investigation.

CONTRAINDICATIONS

Hypersensitivity to product ingredients or sulfonamides. Kidney disease.

WARNINGS

Pregnancy: Safe use not established. Teratogenic potential of sulfonamides not thoroughly investigated. However, a significant increase in the incidence of cleft palate and other body abnormalities of offspring was observed when sulfonamides were given to pregnant rats and mice at high oral doses. Usefulness of sulfonamides is limited due to increasing frequency of resistant organisms.

Sulfonamide associated deaths were reported from hypersensitivity, agranulocytosis, aplastic anemia, other blood dyscrasias. Early clinical indications may be sore throat, fever, pallor, purpura, jaundice.

Discontinue on evidence of systemic toxicity.

PRECAUTIONS

Give with caution to patients with impaired renal or hepatic function, severe allergy or bronchial asthma.

Maintain adequate fluid intake to prevent crystalluria and stone formation. In glucose-6-phosphate dehydrogenase deficient individuals, hemolysis may occur. (Frequently dose related.)

ADVERSE REACTIONS

Blood dyscrasias: Agranulocytosis, aplastic anemia, thrombocytopenia, leukopenia, hemolytic anemia, purpura, hypoprothrombinemia and methemoglobinemia.

Allergic reactions: Erythema multiforme (Stevens-Johnson Syndrome), generalized skin eruptions, epidermal necrolysis, urticaria, serum sickness, pruritus, exfoliative dermatitis, anaphylactoid reactions, periorbital edema, conjunctival and scleral injection, photosensitization, arthralgia, and allergic myocarditis.

Gastrointestinal reactions: Nausea, emesis, abdominal pains, hepatitis, diarrhea, anorexia, pancreatitis, and stomatitis.

C.N.S. reactions: Headache, peripheral neuritis, mental depression, convulsions, ataxia, hallucinations, tinnitus, vertigo and insomnia.

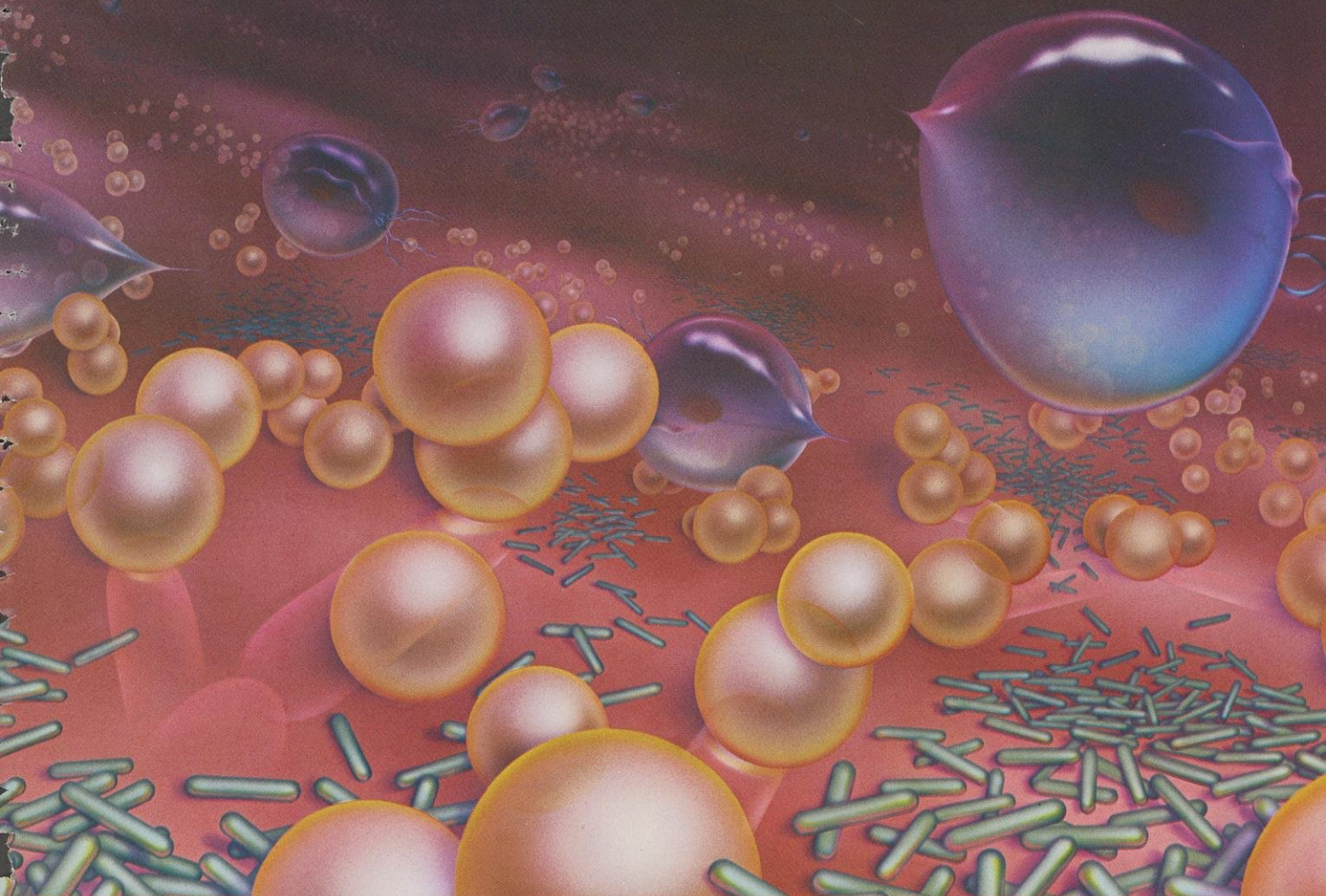
Misc.: Drug fever, chills, and toxic nephrosis with oliguria and anuria. Periarteritis nodosum and L.E. phenomenon. Sulfonamides bear chemical similarities to some goitrogens, diuretics (acetazolamide and the thiazides), and oral hypoglycemic agents. Goiter production, diuresis, and hypoglycemia have occurred rarely. Cross-sensitivity may exist with these agents.

Rats appear to be especially susceptible to the goitrogenic effects of sulfonamides. Long-term administration has produced thyroid malignancies in the species.

SYNTEX

SYNTEX LABORATORIES, INC.
PALO ALTO, CALIFORNIA 94304

Artist's rendition of frequently encountered organisms:
Trichomonas vaginalis, *Candida albicans*, and *Haemophilus vaginalis*



VAGINITIS*

VAGITROL®

CREAM

(sulfanilamide 15.0%, allantoin 2.0%,
aminacrine hydrochloride 0.2%)

SUPPOSITORIES

(sulfanilamide 1.05 g, allantoin 0.14
aminacrine hydrochloride 0.014 g)

Usually uncomfortable and embarrassing, your patient wants fast relief.

Prompt symptomatic relief[†] of itching,
burning, discharge, malodor...

Often more than one pathogen is
involved.

... when the specific organism is unknown.

*This drug has been evaluated as probably effective for this indication.
See brief summary.

See preceding page for summary of prescribing information.