WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 8.453
Volume 13, Issue 22, 359-371. Review Article ISSN 2277–7105

SULFACETAMIDE AND ITS VARIOUS FORMULATIONS IN MARKET: AN OVERVIEW

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Article Received on
25 Sept. 2024,

Revised on 16 Oct. 2024,
Accepted on 06 Nov. 2024

DOI: 10.20959/wjpr202422-34601

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1. ABSTRACT

Topical formulations are intended for application on the skin and generally cause fewer systemic side effects than oral medications. They include creams, ointments, lotions, gels,etc. The type of skin or the severity of the disease determines the topical formulation used. Sulfacetamide is a sulphonamide antibacterial that has been employed as a topical formulation in various ophthalmic, dermatological, and hair solutions to treat bacterial infections, acne, and scalp conditions. It targets bacterial folic acid synthesis as the mechanism, and its effective activity ranges across various gram-positive and gram-negative bacteria. It, however poses some challenges with regards to its bioavailability due to a problem with poor penetration across the eye in its ophthalmic preparations through eyedrops. Innovations like hydrogels and sustained release inserts seek to prolong the retention period and patient compliance. The type of application does have differing side effects; for instance, there are irritation, liver issues, and even blood dyscrasias. Specific groups, such as pregnant women and pediatric patients, are cautioned to be careful with the use of this drug. Continuous improvements of topical delivery systems continue in the quest to optimize the therapeutic outcome, reduce side effects, and expand clinical applications of sulfacetamide for safe and effective treatment of dermatological and ocular infections.

KEYWORDS: Topical Formulations, Anti-Bacterial, Sulfacetamide, Bio-availability.

2. INTRODUCTION

Topical preparations are crucial for the delivery of drug directly to the skin. This allows for higher doses while reducing systemic side effects compared to systemic drugs. Their

application often is cumbersome and time consuming. They consist of a vehicle optimized for some kind of problem in the skin and an active ingredient, which is usually a drug or a plant. The degree of penetration of the active principle depends on several factors, which may be physiological. For the treatment with a full course, the prescriber will take account of the delivery vehicle, treatment area, and duration of application. In general, for an adult it would require 20-30 g of cream or ointment to cover all the body parts. Topical preparations are available in several forms: lotions, creams, emulsions, pastes, aerosol foams, powders and transdermal patches. The type of vehicle is determined by the skin type: for instance, creams are acceptable for moist skin conditions but ointments can be applied on dry skin. If inflammation persists, wet compresses are often recommended; if cracks and sores exist, then bland applications are acceptable. Finally, formulations suitable for neonates are also required because they possess an immature barrier in their skin.[1] Some topical drugs are also hazardous during pregnancy and breastfeeding. Besides that, the gut's mucous membrane is also a filter for oral materials to be transferred in that it allows nutrients to pass through but screens off harmful materials. The glycoproteins, enzymes, and electrolytes comprising the mucus layer can interfere with oral nanocarriers' potential for gut retention.[2] A history of medicine is incomplete without mentioning the 1930s discovery related to the antibacterial properties of a specific dye-a tremendous improvement in the medical therapy. Prontosil was a compound found due to the discovery by Domagk, which brought up the start of modern antibiotics. Subsequent work demonstrated that prontosil is converted in vivo to a very active compound, sulphanilamide. This ultimately led to important advances in the treatment of bacterial infections and brought Domagk the Nobel Prize in Medicine for the year 1939.

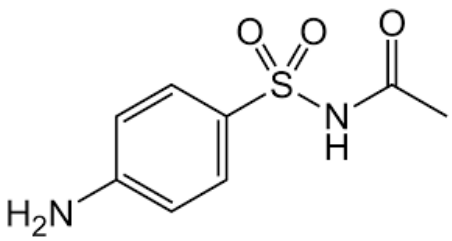

Fig. 1: Structure of Sulfacetamide.

The broad-spectrum antibacterial agent sulfacetamide is often applied to treat eye infections and acute conjunctivitis, mainly in its sodium form (SCS) with a concentration of 30% for various infections. The ease and low cost with which eye drops are administered have assured their continued popularity as a delivery system, but poor ocular bioavailability has severely

restricted their effectiveness, largely because these drops so often fail to penetrate the internal structures of the eye.[3]

Recent pharmaceutical research has been dominated by innovative drug delivery approaches, and hydrogels rank among the favourites for enhanced drug delivery. These three-dimensional polymer networks can be blended with a wide range of ophthalmic drugs and, hence, better tolerance by patients can be achieved by increasing the retention of drug in the eye than the traditional formulations. The drug may be administered to the eye by local routes, systemic routes, or intraocular routes. Topical administration is very common but it suffers from problems through high losses in the pre-corneal space. Systemic methods require higher blood levels and carry the risk of unwanted effects, and intraocular injections, though effective in delivering drugs to deeper structures, carry risks of haemorrhage and retinal detachment. Overall, improving ocular drug delivery systems is important to achieve an effective therapeutic concentration in eye tissues with minimal side effects and maximized patient safety.[4]

Sulphonamides have a bacteriostatic activity. They competitively inhibit dihydropteroate synthase, the bacterial enzyme for the incorporation of para-aminobenzoic acid (PABA) into dihydro- pteroic acid, the immediate precursor of folic acid.[5] The sulphonamide-sensitive microorganisms have to synthesize their own folic acid, whereas those bacteria that can use already formed folate are unaffected. Mammalian cells require preformed folic acid and are, therefore usually not adversely affected by sulphonamides.[6]

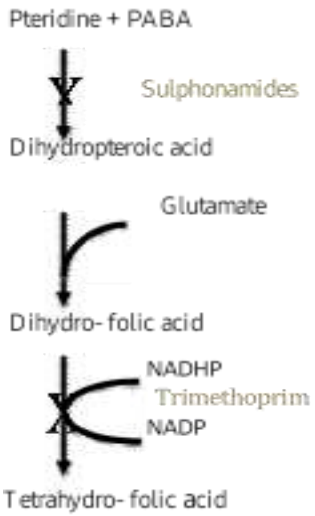

Fig. 2: Mechanism of Action of Sulphonamides.

Sulfacetamide is a synthetic bacteriostatic antibiotic that inhibits the synthesis of both dihydro-folic acid and para-aminobenzoic acid the latter is required in bacterial growth.[7] It is apparently active against most of the Gram-positive and many Gram-negative organisms, especially enteric bacteria and eubacteria.[8,9] Some bacteria are sensitive to sulfonamide or to all its forms. Sulfacetamide is harmful to soil organisms and might be resistant to all forms of bacterial growth. Thus, sulfonamides are essential for inhibition of bacterial growth and survival.[10,11]

Sulfacetamide is one such medication that is completely absorbed through the oral route with plasma protein binding ranging between 80-85% and is metabolized by the liver to produce the inactive metabolites. It possesses a half-life between 7-12 hours, and biotransformation methods include acetylation, conjugation with sulphate or glucuronic acid, and some oxidative pathways. Some of the biotransformations have also been observed to be species-specific.[12] For instance, dogs show poor acetylation with minimal antibacterial activity. Mostly excreted in urine, but secreted through milk, faeces, and bile are much less important.[13]

- **Absorption:** Most of the sulfonamides specially sulfacetamide that are well absorbed. Complete absorption is shown with more than 90 percent of the dose recovered in urine as the parent drug and metabolites while incomplete absorption is shown with lower recoveries.
- **Distribution:** After absorption, sulfonamides are highly distributed throughout the body, penetration into various bodily fluids and tissues, and circulation to the fetus via the placenta. Their Vd ranges between 10-30 L/kg or equating to 15-40% of the total body volume.[14]
- **Metabolism:** The major metabolizing organ of sulfonamides is the liver. However, N-acetylation and N-glucuronidation are other metabolizing processes which vary with different organs in the degree of metabolism. In such metabolism, Cytochrome P-450 enzymes play a prominent role.[15]
- **Excretion:** Renal excretion is the main mode of elimination of sulfonamides and their metabolites since more than 90% of them are eliminated through kidneys. Most of the sulfonamides are excreted both through passive and tubular excretion, and N-acetyl metabolites in general have higher renal clearance than the parent drug. The renal clearances of hydroxy sulfonamides are also increased along with water solubility that favors their elimination.[16]

2.1. Types of Topical Preparations based on site of application:

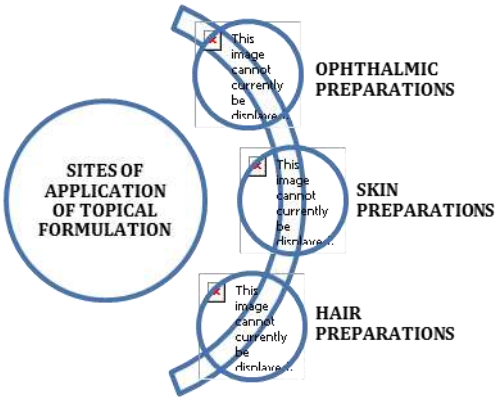

Fig. 3: Various Topical Preparations based on Site of Application.

Conjunctivitis and other superficial ocular infections caused by susceptible microorganisms, such as Escherichia coli, Staphylococcus aureus, Streptococcus pneumoniae, viridans group streptococci, Haemophilus influenzae, Klebsiella species, and Enterobacter species, can be treated with ophthalmic ointment and solution. Ophthalmic solution: Using it in conjunction with systemic sulphonamide treatment to treat trachoma Usage restrictions: Sulphonamides used topically do not offer sufficient protection against Pseudomonas aeruginosa, Serratia marcescens, and Neisseria species. Additionally, a sizable portion of staphylococcal isolates exhibit total resistance to sulpha medications.[17]

Sulphonamides show some Adverse effects as follows:
Blood dyscrasias: Sulphonamides have been linked to severe responses (rare deaths) such as aplastic anemia, agranulocytosis, and other blood dyscrasias (independent of route). At the first indication of a significant response, stop.

Dermatologic reactions: Sulfonamides have been linked to severe responses (rare deaths), such as toxic epidermal necrolysis and Stevens-Johnson syndrome, regardless of the route. Stop as soon as a rash appears.

Hepatic necrosis: Sulfonamides, regardless of the route, have been linked to uncommon deaths linked to fulminant hepatic necrosis. At the first indication of a significant response, stop.[17]

Table 1: Various Ophthalmic preparations of Sulfacetamide Sodium in market.

Sr No.	Brand Name	Active Ingredient	Inactive Ingredient	Uses	Company Name	Picture	Reference
1.	Bleph-10 (Eye Drop)	Sulpacetamide Sodium 10%	Belzalkonium Chloride, Sodium Hydroxide	Treatment Of Bacterial Conjuncti Vities And Other Superficial Eye Infections	Pfizer		[29]
2.	Blephamide (Eye Drop)	Sulfacetamide Sodium 10% And Predesolone Acetate 0.5%	Edetate Disodium, Poloxamer 407 Boric Acid, Naoh/Hcl Water For Injection	Treatment Of Bacterial Conjuncti Vities And Other Superficial Eye Infections With Inflammation	Allergan		[30]

Some precautions need to be taken while using ophthalmic formulation include

Information for patient: To avoid contamination, do not touch tip of container to the eye, eyelid or any surface.

Drug interaction: Sulfacetamide preparations are incompatible with silver preparations.

Carcinogenesis, Mutagenesis, Impairment of Fertility: No studies have been conducted in animals or in humans to evaluate the possibility of these effects with ocularly administered sulfacetamide. rats appear to be especially susceptible to the goitrogenic effects of sulfonamides, and long-term oral administration of sulfonamides has resulted in thyroid malignancies in these animals.

Pregnancy: It is not known whether topically applied sulfonamides can cause fetal harm when administered to a pregnant woman. this product should be used in pregnancy only if the potential benefit justifies the potential risk to the fetus.

Pediatric use: safety and effectiveness in infants below the age of two months have not been established.[18]

Acne and other skin disorders (such rosacea and seborrheic dermatitis) are treated with sodium sulfacetamide. It aids in reducing the skin irritation symptoms brought on by these illnesses. Sulfacetamide and sulphur are two medications that are combined in this formulation. Sulphur and sulfacetamide both prevent germs from growing on the skin's surface. Additionally, sulphur helps the skin shed old cells by drying it up. Adverse Reactions Dry skin and mild redness are possible. Notify your doctor or pharmacist right once if any of these side effects persist or worsen. Keep in mind that your doctor has recommended this

medicine because he or she believes it will help you more than it will harm you. Serious adverse effects are uncommon in many patients taking this medicine. Stop taking this medicine and notify your doctor immediately if you have any severe adverse effects, such as skin irritation or skin scaling. If you take this medication on raw or damaged skin, you may be more susceptible to adverse effects. For specifics, speak with your physician. It is uncommon for this medication to cause a very significant adverse response. However, seek immediate medical attention if 12 and above, sulfacetamide sodium topical (for the skin) is used to treat acne, dandruff, seborrheic dermatitis (an inflammatory skin disorder of the scalp), and certain skin infections.[19]

Skin preparations of Sulphonamides show various Adverse effects as follows:
If you have symptoms of a severe skin response (fever, sore throat, burning eyes, skin discomfort, red or purple skin rash with blistering and peeling) or an allergic reaction (hives, difficulty breathing, swelling in your face or throat), you should seek immediate medicalattention. Serious adverse effects are possible with sulfacetamide sodium topical. Call your doctor right away and stop taking sulfacetamide sodium topical if you have:
Low blood cell counts fever, chills, fatigue, mouth sores, skin sores, easy bruising, unusual bleeding, pale skin, cold hands and feet, feeling lightheaded or short of breath.

Liver issues dizziness, nausea, vomiting, upper right side stomach pain, fatigue, itching, dark urine, clay-colored stools, jaundice (yellowing of the skinoreyes).

New or worsening lupus symptoms, such as joint pain and an arm or face rash that gets worse in the sun.

- Dry skin.
- JOINT pain, swelling, or stiffness.[19]

Table 2: Various Skin Formulations of Sulfacetamide Sodium in market.

Sr No.	Brand Name	Active Ingredient	Inactive Ingredient	Uses	Company Name	Picture	Ref
1.	Kalron (Skin Lotion)	Sulfacetamide Sodium 10%	Hydroxy Ethyl Cellulose, Propylene Glycol	Bacterial Conjunctivitis, Blepharitis, Acne Vulgaris	Padagis Israel Pharmaceut Icals		[31]
2.	Ovace Plus (Skin Cream)	Sulfacetamide Sodium 10%	Benzyl Alcohol, Polysorbate 60 Propylene Glycol	Treatment Of Acne Vulgaris	Mission Pharmacal Company		[32]

3.	Eczim (Skin Lotion)	Sulfacetamide Sodium 10% , Sulfer 5%	Benzalkonium Chloride, Hydro Chloric Acid	Treatment Of Acne Vulgaris	West-Coast Pharmaceu Ticals Works Ltd		[33]

Some Precautions need to be taken care while using skin preparations which are as follows:
For external use only. Keep away from eyes. If irritation develops, use of the product should be discontinued and appropriate therapy instituted. Patients should be carefully observed for possible local irritation or sensitization during long-term therapy. Kernicterus may occur in the newborn as a result of treatment of a pregnant woman at term with orally administered sulfonamide. There are no adequate and well-controlled studies of Sodium Sulfacetamide Lotion in pregnant women, and it is not known whether topically applied sulfonamides can cause fetal harm when administered to a pregnant woman.

It is not known whether sodium sulfacetamide is excreted in human milk following topical use of Sodium Sulfacetamide Lotion. Safety and effectiveness in pediatric patients under the age of 12 have not been established. Apply a thin film to affected areas twice daily.[20]

Topical agents and synthetic drugs used for dandruff treatment have specific side effects including burning at the application site, depression, dizziness, headache, itching or skin rash, nausea, stomach pain, vision change, vomiting, discoloration of hair, dryness or oiliness of the scalp and increased loss of hair. Thus, essential oils and extracts from plants could be valuable in the treatment and prevention of dandruff.[21] Topical antifungals are considered the first line of treatment for dandruff including azoles, with clotrimazole (1%), ketoconazole (2%), and miconazole (2%). Other commonly used therapies integrate benzoyl peroxide, coal tar, glycerin, zinc pyrithione, lithium succinate/gluconate, salicylic acid, selenium disulfide/sulfide, sodium sulfacetamide, etc. Sulfacetamide sodium is used to treat certain scalp conditions (dandruff, seborrhea). These scalp problems can sometimes be worsened by bacteria on the skin. This medication works by stopping the growth of certain skin bacteria. Sodium sulfacetamide belongs to a class of drugs known as sulfa-antibiotics.[22]
Such Preparations show certain unwanted adverse effects which are as follows:

- Irritation of the skin or scalp may occur. If this effect lasts or gets worse, stop using this medication and tell your doctor or pharmacist promptly.
- rash
- itching/swelling (especially of the face/tongue/throat)

- severe dizziness
- trouble breathing
- A very serious allergic reaction to this drug is rare.[23]

Table 3: Hair Formulation of Sulfacetamide Sodium in market.

Sr No.	Brand Name	Active Ingredient	Inactive Ingredient	Uses	Company Name	Picture	Reference
1.	Ovace Plus (Hair Shampoo)	Sulfacetamide Sodium 10%	Sodium Laureth Sulfate, Methyl Paraben, Purified Water	Treat Scalp Conditions (Dandruff, Seborrhea)	Mission Pharmacal Company		[34]

Drug Interaction:- Drug interactions may change how your medications work or increase your risk for serious side effects.

Pregnancy:-During pregnancy, this medication should be used only when clearly needed. Discuss the risks and benefits with your doctor.

Store at room temperature. Avoid freezing and high heat. This medication may darken slightly over time. This slight darkening does not change the effectiveness or safety of the medication.

Keep all medications away from children and pets.[23]

3. VARIOUS TOPICAL FORMULATIONS OF SULFACETAMIDE SODIUM

Engelbrecht et al There are four categories of microbial pathogens: bacterial, viral, fungal, and parasitic. There are topical ocular preparations available from a pharmacological perspective although some systemic agents are occasionally required for particular infections. Aciclovir administered both topically and orally is very crucial in herpetic ocular infections but infections by fungi or parasites are very resistant and should be referred to a specialist for management. Sulphacetamide is a sulphonamide, a bacteriostatic antibiotic, that can be used for treating some conditions.[24]

Nagpal et al have studied controlled release ocusert of sulfacetamide sodium for the treatment of bacterial conjunctivitis. Hydroxyl propyl methyl cellulose K-15 and Ethyl cellulose were employed as polymers at various concentrations and combination for its synthesis. The in-

vitro release study has been used for estimating physiochemical parameters of ocuserts like thickness, weight, and moisture absorption. The formulation F9 was found to possess good in-vitro release properties for Sulfacetamide sodium. PVA as well as HPMC is a promising hydrophilic film-forming polymer. The ocuserts were smooth, soft, uniform in thickness as well as weight, did not show any microbial growth, and possessed sustained-release properties.[25]

Sheshala et al tried to develop an in situ ocular sustained release gel with sufacetamide sodium with the assistance of pH-induced gelling polymers. The prepared formulations were evaluated for appearance, pH, viscosity, gelling capacity, drug content, and in vitro drug release. Clear free-flowing gels were produced with high viscosity and controlled drug release. It was compared with the commercially available eye drops that proved the chosen formulation possessed nearly equal antimicrobial activity and therefore, Carbopol®/HPMC-based in situ gels can enhance the compliance of patients.[26]

The present method by Alaallah et al. is a simple, low-cost, precise, and speedy spectrophotometric method for the evaluation of sulfacetamide sodium. It is based on the conversion of sulfacetamide sodium to diazonium salt followed by reaction with p-cresol in alkaline media. This is a recovery, environmentally friendly method; the linear range and detection limits are high.[27]

Karnik et al. explored in vitro release of a fixed-dose combination of Prednisolone Sodium Phosphate and Sulfacetamide Sodium from hot-melt extruded bioadhesive ophthalmic inserts in the treatment of various ocular bacterial infections, showing that inserts sustained their performance, retarded drug flux, and showed stability over a range of temperatures.[28]

4. CONCLUSION

Sulfacetamide topical formulations with targeted antibacterial activity are very useful for ocular, dermatological, and scalp treatments. This reduces systemic exposure and side effects. Hydrogels and ocuserts have further enhanced drug retention, but more importantly, patient compliance in ophthalmic formulations. However, sulfacetamide has broad-spectrum bactericidal activity, and therefore, it needs proper monitoring since it is known to cause some side effects and interactions with certain drugs. Sulfacetamide continues to enhance efficacy and safety of localized therapeutic applications through tailoring of formulations based on specific skin types, patient needs, and treatment areas.

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